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TITLE: DIABETES CARE AND TREATMENT PROJECT: A JOSLIN TELEMEDICINE INITIATIVE

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14. ABSTRACT

This is a final report on the work accomplished during the period of performance from 2003 to 2007 with Joslin Diabetes Center as the prime organization. As of October 2007, under agreement with Joslin, this project was relocated to University of Hawaii as a new contract. The program proposed for this final year will not change but the organization supporting the performance becomes the University of Hawaii. We have completed all deliverables outlined in the Statement of Work and are in the process of completing the proposed clinical studies under the new contract through University of Hawaii. The proposed studies are all under active HSRRB approvals and are either in final recruitment, data analysis, or have been completed with manuscripts either accepted for or under review in appropriate peer reviewed journals. The application is currently being integrated into AHLTA. Technologically, our work on image quality improvement for retinal images has resulted in a digital camera optimized for low light level, non-pupil dilation acquisition and we have developed an image deconvolution algorithm that improves image quality through post image acquisition processing. CDMP development now incorporates a patient portal for home monitoring devices in collaboration with iMetrikus. CDMP development is ongoing for robust computer assisted decision support applications as the program is moved to University of Hawaii.

15. SUBJECT TERMS

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INTRODUCTION

The major goals of this project were the establishment of a telemedicine system for comprehensive diabetes management and the assessment of diabetic retinopathy that a) provides increased access for diabetic patients to appropriate care, b) centralizes the patients in the care process, c) empowers the patient to better manage their disease, d) can be performed in a cost effective manner, and e) maintains the high standard of care required for the appropriate management of diabetic patients.

As part of this program we performed appropriate clinical validation, cost efficiency, and risk benefit studies associated with the use of the Comprehensive Diabetes Management Program (CDMP) and the Joslin Vision Network (JVN) Eye Health Care Program that is now a module of the CDMP. The work performed here also had a secondary focus of continuing the ongoing research associated with the development of new modules for the CDMP, and the development and validation of computer algorithms designed to automate detection of retinal lesions developed during the course of retinopathy development and automate decision support associated with appropriate follow up eye care.

The need for diabetes disease management is driven by the knowledge that diabetes is not currently curable; but it is treatable and its complications are preventable through optimal care- and self-management. However, the traditional physician-centered, episodic, acute-care model is not designed to optimize care-and self-management, especially with large numbers of diabetic patients (2,200 new cases diagnosed every day in the US). To do requires that the health care delivery system be re-engineered. Such re-engineering is a reality with the use of the CDMP developed under this collaborative effort.

BODY

Summarized below is the originally proposed Statement of Work (SOW) for reference:

1. Prospective multi center cost efficiency study performed using the JVN Telehealth Eye Care module
2. Prospective multi-center risk benefit study using the JVN Telehealth Eye Care module
3. JVN Telehealth CDMP program usability and impact on clinical workflow study
4. Prospective multi-center clinical outcomes efficacy and cost efficiency study using the JVN Telehealth Comprehensive Diabetes Management Program
5. Clinical validation of the Behavior Assessment Tool (BAT) developed for the JVN Telehealth CDMP application
6. Development and validation of Learning Level Assessment and Readiness to Learn tools for the JVN Telehealth CDMP application
7. Deployment of JVN Telehealth CDMP application in Tripler Army Medical Center and Honolulu VA in Hawaii
8. Deployment of JVN Telehealth CDMP application in VA VISN 1 network
9. Deployment of JVN Telehealth CDMP application into the Department of Defense TRICARE Online computer system
10. Establish a centralized JVN Telehealth clinical coordination center to facilitate the proposed multicenter clinical trials
11. Clinical validation of the JVN Eye Care computer algorithm for automation of detection of retinal lesions
12. Clinical validation study for the JVN developed retinal imaging device
13. Automation of the retinal image taking process using the JVN developed retinal imaging device
14. Migration of JVN Eye Care module to Microsoft .Net operating platform
15. Development of additional modules for the JVN Telehealth CDMP application to include an outcomes and reporting module, an education scheduling and tracking tool, a knowledge assessment tool, a nutrition module, a patient portal module, integration of wireless home monitoring devices, and a primary care practitioner module

The proposed prospective studies noted above are summarized below at a program level. Additional progress on other efforts are also presented in each site section summary. The participating sites are Joslin Diabetes Center, Department of Defense at Walter Reed Army Medical Center, VA at VAMC Jamaica Plain campus in Boston, and the participants through University of Hawaii.

1. Summary Status Report for Clinical Research Projects

The following describes the purpose and methods of the 6 clinical and observational studies associated with this project, and then gives a status report for each.

1. Prospective cost efficiency study performed using the Telehealth Eye Care Module. The purpose of this study is to compare the costs and cost-effectiveness of the Telehealth Eye Care module with conventional clinic-based eye examinations among a diabetic cohort receiving annual eye examinations. The Eye Care Module is a digital teleophthalmology system developed by the Beetham Eye Institute at the Joslin Diabetes Center in cooperation with the Departments of Defense and Veterans Affairs. The research design for this study is a randomized clinical trial that will provide prospective data for insertion into decision models. In turn, the decision models will generate the data to evaluate the cost-effectiveness of the Eye Care Module versus conventional clinic-based eye examinations. Consenting patients (n = 243) at sites of the Walter Reed Army Health Care System (WRHCS) with type 1 or type 2 diabetes mellitus and scheduled for eye examinations on an annual basis will be enrolled in the study and randomized to conventional clinic-based eye examinations or eye examinations performed by the Telehealth Eye Care Module (plus an assessment of visual acuity). Subjects will be followed for one year. The study will track all costs that accrue over that year in the provision of care for both modalities, including labor, equipment, travel for the study subjects, and lost wages/productivity for study subjects, among others. Cost-effectiveness will be measured based on study subjects' compliance with the clinical eye examination and follow-up recommendations and diagnostic and treatment outcomes. We will *a priori* generate cost-effectiveness data based on diagnoses of diabetic retinopathy and macular edema. In a cost consequence analysis, we will consider other diagnostic outcomes and outcomes in aggregate. Additionally, we will impute cases of expected vision loss and, therefore, project differences in the number of cases of vision loss averted between modalities.

Progress to date: Since we received initial funding, the investigators designed this study, wrote the research protocol, obtained approval from all necessary human subjects review boards, trained the study staff in the procedures of the Telehealth Eye Care Module, and enrolled study subjects (n = 108 as of 10/25/07). Enrollment of study subjects and tracking of currently enrolled subjects with respect to the study outcomes is ongoing (See Table 1). ***This study will be completed under the new contract with University of Hawaii***

2. Prospective risk benefit study using the Telehealth Eye Care Module. The overarching hypothesis of this study is that tele-retinal imaging supplemented with a non-invasive eye care assessment (hereafter referred to as a Technology Assisted Ophthalmic [TAO] examination) in patients with diabetes can substitute for a complete eye examination with a dilated fundus evaluation. The study, however, tests specific hypotheses about the level of agreement between the TAO and complete eye examinations at baseline and over time. To do so, the study involves a two-arm, open, parallel group design in which participants will have both a TAO exam and a complete eye exam. Results from the two exam modalities will be compared for level of agreement, sensitivity, specificity and predictive value for the following outcome measures: eye care referrals, level of diabetic retinopathy, and the presence of other referable non-diabetic ocular disease. A cost effectiveness analysis will also be completed. The study will enroll 500 participants from the VA Boston Healthcare system to initially evaluate the baseline level of agreement of the TAO examination and a complete eye exam. This provides the best opportunity for assessing agreement in diagnosing all levels of diabetic retinopathy, non-diabetic ocular pathologies and referral for further eye care. Approximately 35-40% of these participants will require referral for eye care, based on findings from the initial examination. We will then follow the subset of individuals with no diabetic retinopathy or mild retinopathy (approximately 300 participants) with annual examinations (both TAO and complete eye exams) over a 2-year period to determine their level of agreement and the incidence of new retinopathy and/or non-diabetic eye disease. In this setting we will also assess the economic impact of tele-retinal imaging in comparison to a complete eye examination, using a cost-minimization approach.

This study receives additional support from a VA Health Services Research and Development grant.

Progress to date: This study is actively recruiting and tracking subjects (n = 108 as of 10/25/07). ***This study will be completed under the new contract with University of Hawaii***

The results from this study will directly impact on the role Tele-retinal imaging can play in the care of patients with diabetes. This trial will prospectively evaluate the clinical benefit and economic impact of an enhanced

tele-retinal imaging exam in screening patients with diabetes for eye diseases in distinction to prior modeled analyses.

3. Human Factors study of the CDMP: Usability Lab. This study followed an Expert Review (see Table 1) of the CDMP, conducted by the American Institutes for Research and funded separately. The purpose of this study was to conduct a usability test of the CDMP under controlled laboratory conditions. In brief, the CDMP is an Internet-based Informatics tool that has numerous functions for facilitating and improving care and tracking of patients with diabetes. We were interested in learning whether the CDMP is "user-friendly" and compatible with diabetes care providers' normal workflow. The study design involved recruiting diabetes care providers (N = 6) and asking them to use the CDMP to perform tasks simulating actual patient encounters in the ambulatory care setting. Study participants were asked to 'think aloud' as they used the CDMP. They were then debriefed at the completion of a 2-hour session, and a questionnaire was administered to them to collect qualitative data regarding their subjective impressions. The results of the study were used to identify opportunities for improving the system's usability.

Progress to date: All aspects of data collection for this study have been completed and we have made many of the changes suggested by the study participants. In May 2006, we presented a poster reporting the study design and preliminary results at the American Telemedicine Association (Bursell SE, Birkmire-Peters D, Conlin PR, Fonda SJ, Kedziora RJ, Paulsen C, Perkins J, Rodbard D, Vigersky R. May 2006. Human Factors Analysis: Joslin Diabetes Center Comprehensive Diabetes Management Program. *American Telemedicine Association*, Annual Meeting, San Diego, CA.). The poster was awarded a blue ribbon by peer review. Lastly, a paper describing the study is was published in *Diabetes Technology and Therapeutics* (Fonda SJ, Paulsen CA, Perkins J, Kedziora RJ, Rodbard D, Bursell SE. Usability Test of an Internet-based Informatics Tool for Diabetes Care Providers: the Comprehensive Diabetes Management Program).

4. CDMP usability and impact on clinical workflow study. This project examined the usability and impact on clinical workflow of the CDMP in the WRHCS. The project examined the CDMP's usability and impact on clinical workflow by comparing them to those of the existing, baseline health information system in the WRHCS. Specifically, we examined the Diabetes Health*e*Card data (which documents the process and quality measures of the Diabetes Quality Improvement Program (DQIP)) of selected diabetes health care providers and administer questionnaires regarding aspects of the diabetes care system before and after adoption of the CDMP. In addition, we evaluated the use of the CDMP by observing the interactions of these care providers with standardized patients (i.e., actors who have been trained to provide a realistic initial or follow-up history for a simulated patent). Finally, we will use structured focus group discussions with the providers lead by a trained, experienced facilitator. Health care providers selected for this study were the Nurse Practitioners (NPs) of the Diabetes Institute of the WRHCS.

Progress to date: The data collection portion of this study is complete and we have drafted a full report. The report will provide the basis for further modifications to the CDMP. At this time, we do not expect to submit the study results for publication.

5. **Prospective clinical outcomes efficacy and cost efficiency study using the CDMP (Internet-based Diabetes Education and Case Management).** We will examine the efficacy and cost-effectiveness of two methods of diabetes education and care management -- a traditional model that involves face-to-face encounters and telephone contact and an Internet-based model using a diabetes care management web site. We will compare these interventions to a usual care control group that receives no education or care management but is provided with Internet access. This study employs a randomized, prospective, parallel group design involving patients with diabetes mellitus. Primary outcome measures include clinical data (e.g. HbA1c, blood pressure, quality of life questionnaires) and secondary outcome measures include economic data (e.g. costs of case management, medication usage, and number(s) of ER visits/hospitalizations during the study period). We will study 150 participants with elevated HbA1c (³ 8.5%). Over 12-months we will measure HbA1c, office BP, and scores on the Problem Areas in Diabetes (PAID) questionnaire and Center for Epidemiologic Studies Depression Scale (CES-D). Participants receiving usual care will receive a notebook computer and Internet access. Those assigned to Internet-based care management will receive a notebook computer, Internet access and will interact with a care manager through a diabetes education and care management web site. Those receiving traditional care management will interact with a care manager following

a structured contact schedule. Both care management models will employ medication algorithms to improve glucose and BP control, with the secondary goal of also improving diabetes-related stress and depression. We will collect data on process measures and health care utilization in order to conduct exploratory analyses on the cost-effectiveness of these interventions.

Progress to date: The project is fully enrolled (152 patients) and final participant evaluations have taken place. Data analyses are now in progress. ***This study will be completed under the new contract with University of Hawaii***

The potential impact resulting from this study is that care management programs that deliver specialized services to patients with poorly controlled diabetes mellitus may ultimately reduce the drain on resources from diabetes and its complications. An Internet-based care management model may prove to be more cost-effective can be delivered directly to patients in their home. Such a clinical initiative that successfully improves compliance with clinical guidelines will improve the care of such high-risk patients.

6. Clinical validation of the Behavior Assessment Tool (BAT) developed for the CDMP application (including test-retest reliability and validity). The Behavioral Assessment Tool (BAT) was developed as a stand-alone module within the CDMP. It is a screening questionnaire containing questions about psycho-social factors, nutrition, physical activity, alcohol and tobacco use, medications, general health, self-monitoring of blood glucose and economic factors. There are two studies associated with testing its reliability and validity -- An Assessment of the Test-Retest Reliability of the CDMP BAT and An Assessment of the Validity of the CDMP BAT (See Table 1).

The reliability assessment is a multi-site observational study with two measurements per study subject taking place 2 to 4 weeks apart. The sites are: the VA Boston Healthcare System (n = 42), Joslin Diabetes Center (n = 43 – with the additional subject being approved by the IRBs), Walter Reed Army Medical Center (n = 42), and community health centers in Hawaii (n = 42). The study protocol involves recruiting English-speaking individuals who are 20+ years of age and have type 1 or 2 diabetes. Eligible and interested participants are administered the following: a) an Informed Consent; b) a test to assess executive/cognitive function; c) questions about their social-demographics; and d) the BAT. Two to four weeks later, participants are asked to complete the same procedures (excluding the Informed Consent and questions about social-demographics). In addition, the study reviews participants' medical records to obtain their most recent A1c measure, Body Mass Index (BMI), and blood pressure. This information might be examined to help explain any low correlations between BAT responses over time.

Progress to date on Relaibility Studies: The VA, Joslin, and Walter Reed have completed all data collection. We presented a poster of the results for the Joslin site at the CDC Diabetes Translation Conference (Garren, J, Fonda, SJ, Bursell, SE, Conlin, PR, Vigersky RA, Birmire-Peters D. Test-Retest Reliability of a New Screening Questionnaire for People with Diabetes. Poster presented at the CDC Diabetes Translation Conference, Atlanta, April - May 2007). Analyses are ongoing for the VA, Joslin, and Walter Reed sites. The health centers in Hawaii are recruiting study subjects. ***This study will be completed under the new contract with University of Hawaii***

The validity assessment is also a multi-site observational study. This study will examine two types of validity – concurrent and predictive. We will measure concurrent validity by examining how study subjects' responses to its questions correlate with a) their responses to similar questions in other questionnaires administered at the same time, b) recent self-report physical activity and food "logs", c) a cotinine test (to assess smoking status), and d) concurrent health-related factors obtained from their medical records, including current or recent hemoglobin A1c (A1c), current or recent Body Mass Index (BMI), current prescribed medications, and current health conditions. We will measure predictive validity by assessing how study subjects' responses to BAT questions correlate with their future health-related factors, namely health-related factors at six months and twelve months after the BAT administration completed at the beginning of the study as part of Objective 1. The health-related factors we will examine include: new A1c ; new BMI; adherence to recommended foot and eye exams in the intervening period; number of hospitalizations, number of hospital days, and number of emergency room visits in the intervening period; new medications; frequency of provider use and type of provider use in the intervening period; and new health conditions. We are recruiting 75 subjects from Joslin, 75 from Walter Reed, and 75 from the community health centers in Hawaii for this assessment.

Progress to date on Validation: Joslin has completed recruitment and is conducting analyses. As of 10/25/07, 47 subjects have been recruited at Walter Reed. The health centers in Hawaii are initiating recruitment. ***This study will be completed under the new contract with University of Hawaii***

Table 1. Status of Research Studies by Site

Project	Site				Status
	Joslin	Hawaii	WRAMC	VA Boston	
Prospective cost efficiency study performed using the Telehealth Eye Care Module			√		Recruitment ongoing
Prospective risk benefit study using the Telehealth Eye Care Module				√	Recruitment ongoing
Human Factors study of the CDMP: Usability Lab	√				Complete; Manuscript forthcoming in Diabetes Technology and Therapeutics
CDMP usability and impact on clinical workflow study			√		Data collection and initial analyses completed
Prospective clinical outcomes efficacy and cost efficiency study using the CDMP (aka Internet-based Diabetes Education and Case Management)				√	Data collection complete and the last subject has completed the protocol; analyses ongoing
An Assessment of the Test-Retest Reliability of the CDMP BAT	√	√	√		Data collection complete at Joslin, VA and WRAMC; recruitment ongoing in HI
An Assessment of the Validity of the CDMP BAT	√	√	√		Data collection complete at Joslin; recruitment ongoing at WRAMC and in HI
Additional Human Factors Study for the CDMP Application: Expert Review of the CDMP	NA	NA	NA	NA	Completed; suggested changes to CDMP incorporated

Notes: NA means not applicable. The Expert Review of the CDMP did not require recruiting subjects and was done by employees of the American Institutes for Research at their offices.

Deployment of JVN Telehealth CDMP application into the Department of Defense Electronic Medical Record

The overall objective of this study was to incorporate CDMP and related applications into the enterprise electronic medical record (AHLTA). We have three specific objectives: **Objective 1** is to conduct a "proof-of-concept" study that will investigate the feasibility of integrating CDMP's Diabetes Assessment Tool Kit (DATK) into AHLTA. **Objective 2** will evaluate multiple methods of viewing and integrating glucose meter data uploaded through CDMP's Diabetes Mellitus Everywhere (DME) into AHLTA. Once in the CDMP application database the glucose data can be viewed in either the presentation-rich web-based environment of CDMP or in a PureEdge form. We can then incorporate the data into an AHLTA encounter via standard cut-and-paste techniques from CDMP or through the use of PureEdge forms.

In the case of PureEdge forms, we will use the planned capabilities of the product to import data into ALHTA automatically. **Objective 3** is to assess the reliability of the glucose data to provide accurate information when accessed on-line via DME versus a computer in the clinic using proprietary software.

Status:

- As noted above, the Department of Defense has implemented a new electronic medical record (AHLTA) to replace HealtheForces. Deployment of CDMP into HealtheForces at Walter Reed Army Medical Center (WRAMC) was completed in May 2005 but while data is still available for analysis, no new data is being entered into that system. We had initially trained the Diabetes Institute staff at WRAMC in using CDMP in June 2005. However, re-training had to occur in May 2006 so that CDMP could be used in a preliminary way with AHLTA.
- We have begun to integrate the DATK (and plan to integrate the tabular and graphic data which are uploaded from patients' glucose meters into DME) into AHLTA. There is no similar functionality in AHLTA.

Deployment of Telehealth application into community health centers in Hawaii (Deployment was retargeted to Hawaii community health centers in 2006 as both the Tripler Army Medical Center and the VA in Hawaii required that no additional research be conducted until deployment of AHLTA had been completed)

The major goals of this continuing project were the establishment of a telemedicine system for comprehensive diabetes management and the assessment of diabetic retinopathy that provides increased access for diabetic patients to appropriate care, that centralizes the patients in the care process, that empowers the patient to better manage their disease, that can be performed in a cost effective manner, and that maintains the high standard of care required for the appropriate management of diabetic patients. The aim of this program of research will be to perform the appropriate clinical validation, cost efficiency, and risk benefit studies associated with the use of the recently developed Comprehensive Diabetes Management Program (CDMP) and the Joslin Vision Network (JVN) Eye Health Care Program that is now a module of the CDMP. These research studies and the implementation of CDMP were originally planned at Tripler Army Medical Center (TAMC) in Honolulu, HI. Because the decision was made at TAMC to accelerate the adoption of a new electronic medical record (AHLTA), implementation of the CDMP was delayed indefinitely. Consequently, alternative sites in community health centers were chosen for these research studies and the implementation of the CDMP. Waianae Coast Community Health Center, Waianae, HI; The Physicians Center at Mililani, Mililani, HI; and the Molokai General Hospital, Kaunakakai, HI.

Status:

- Three community health centers were identified and are currently participating in the proposed research studies. The community health centers are: Waianae Coast Community Health Center (WCCHC), Waianae, HI; The Physicians Center at Mililani (PCM), Mililani, HI; and the Molokai General Hospital (MGH), Kaunakakai, HI. Subcontracts were let with the Waianae Coast Comprehensive Health Center (April 2006) and Molokai General Hospital (April 2006) to fund CDMP and JVN implementation and ongoing associated personnel costs. Alternative methods for funding the Physician Center at Mililani were identified. Personnel have been hired directly through the Research Corporation of Hawaii (RCUH) for this project. In addition the Koolauloa Community Health Center was awarded a grant from AlohaCare to implement a retinal imaging program into their center. After discussions with personnel from this project, they chose the JVN imaging system and agreed to become a fourth site for our studies
- A subcontract was continued with Estenda Solutions, Inc. to provide technical support for the JVN and CDMP installations and maintenance.
- Kari-Jo Coll, hired through RCUH continues to serve as the JVN retinal image reader for studies done at the three community health centers. A reading station was set up for her in San Jose, CA. Dr. Lloyd M. Aiello from Joslin will serve as the back-up reader. The reading center workstation used by Kari-Jo Coll has been upgraded to JVN version 4.

JVN Imaging Cameras and Acquisition Stations were installed in each of the three community health centers (February 13 -17, 2006). The original equipment has been upgraded in Waianae, and upgrades for the other

clinic imaging workstations are being planned. Additional installation issues were resolved and VPN connections were established. Two staff members were identified for JVN imager training: Darlene Kaahaaina from Waianae Coast Comprehensive Health Center and Radmila Esteron from Molokai General Hospital. Ms. Kaahaaina will also do the JVN imaging for the Physician's Center at Mililani. Both imagers, as well as, Frederick Walsh from Estenda Solutions completed imager training at the Joslin Diabetes Center, Boston, MA, February 27 – March 1, 2006. As of September 2007, 321 patients have been imaged at the three centers.

- The CDMP has been installed at the Physician Center at Mililani and Molokai General Hospital. Given that neither of these centers has an electronic medical record, patients' past two-year medical history must be extracted from charts. This has been initiated and is on-going. Meetings have been held with personnel from Waianae Coast Comprehensive Medical Center to finalize the implementation of the CDMP. Frederick Walsh, Estenda Solutions, is developing the interface for the CDMP with the WCCHC electronic medical record, NextGen.
- Frederick Walsh, Estenda Solutions, and Joseph Humphry, MD, continue to work with the two major laboratories in the state, Diagnostic Laboratory Service, Inc. and Clinical Laboratories of Hawaii, LLP, on the transfer of clinical laboratory data into the CDMP. The Data Transfer Agreements have been signed by the participating health centers. The programming code for the transfer of laboratory data is ready for implementation by Estenda Solutions.

An Assessment of the Test-Retest Reliability of the CDMP BAT and An Assessment of the Validity of the CDMP BAT at Hawaii sites

Refer to the section on Joslin for a brief description of both studies.

Status:

- All three community health centers, Waianae Coast Comprehensive Health Center (WCCHC), the Physician Center at Mililani (PCM), and Molokai General Hospital (MGH), have reviewed descriptions of the Behavioral Assessement Tool Reliability and Validity studies. All three sites are currently enrolling patients into these studies.
- The protocol entitled "An Assessment of the Test-Retest Reliability of the Comprehensive Diabetes Management Program's (CDMP) Behavioral Assessment Tool" was written for the Physician Center at Mililani. The protocol was submitted to the University of Hawaii Committee for Human Studies. It was approved on September 21, 2006. The protocol was also submitted for review to the ORP Human Subjects Research Review Board (USA MRMC). The review was received October 11, 2006. The protocol is currently being revised and prepared for resubmission.

Development of additional modules for the JVN Telehealth CDMP application

The objectives are to develop additional modules that are enhancements to the existing CDMP application. Additional modules will include a medication module, an outcomes and reporting module, an education scheduling and tracking tool, a knowledge assessment tool, a nutrition module, a patient portal module, integration of wireless home monitoring devices, and a primary care practitioner module.

Status: Joseph Humphry, MD, designed a module for incorporation into the CDMP for use by health care providers for recording and displaying patients' medications. Frederick Walsh developed a prototype of the module for review by members of the consortium. This is currently implemented into the CDMP application. Additionally the outcomes and reporting module, and enhanced education module, a nutrition module, the patient portal (DME), and integration of home monitoring devices have all been successfully implemented in the CDMP application. Additionally, we completed negotiations with the 2 laboratory systems in Hawaii (Clinical Laboratory Systems and Digital Laboratory Systems) so that new lab values are automatically downloaded into CDMP and are viewable by both patient and their PCP at the different community health centers

Durham VAMC/Duke University Medical Center SubContract, Dr John Whited, PI

Prospective Economic Analysis of the Joslin Vision Network (JVN) Telehealth Eye Care Module

Status:
The role investigators play at the Durham VAMC and the Duke University Medical Center in this protocol is study design and data analysis. This site was largely responsible for the study design and protocol development. In addition, the statistical support for this project resides at this site. Our site will be responsible for receipt of the data and data analysis. The health economist assigned to this project is at this site and will be responsible for the economic data output and results that are derived from this study.

The following goals have been achieved during the review period:

- IRB approval. We have received initial IRB approval for this project at the Durham VAMC and Duke University Medical Center IRBs. Initial approval from the Durham VAMC was received on July 21, 2006. Initial approval was received from the Duke University Medical Center on June 29, 2006. Dual site approval was necessary since study funds are disbursed at both sites and researchers for this study are based at both sites. Approval for annual continuation review will be sought and obtained when appropriate.
- Study team. The study team has been assembled and has had preliminary meetings in anticipation of receipt of study-related data. The study team consists of John D. Whited, MD, MHS (site PI), Santanu K. Datta, PhD, MBA (health economist), Steven C. Grambow, PhD (supervising statistician), and Amy Jeffreys, MStat (statistician).
- Project management plans. The study team has reviewed the protocol, data collection methods, data analysis plans, and data transmission methods. We have also discussed the web-based interface proposed for use as a means of data transmission. The Health Services Research and Development Service has experience and local expertise with the use of web-based interfaces for data collection and transmission. Once study enrollment commences and we begin to receive study data, the study team will schedule regular meetings to review the progress of the study. Study and data management will be conducted using the Standard Operating Procedures of the Durham VAMC Health Services Research and Development Service. This includes measures to protect the privacy and confidentiality of research data and personal health information.

The analytic plan is as described in the final IRB-approved study protocol. No changes to the protocol are anticipated. However, if any changes are necessary, the site researchers will work with the collaborating institutions to amend the protocol and seek IRB approval for the changes.

Presented at the February 2008 VA HSR&D National Meeting in Baltimore.

The Use of Teleophthalmology for Diagnosing Diabetic retinopathy and Macular Edema

Santanu K. Datta, PhD, MBA and John D. Whited, MD, MHS, Center of Excellence in Primary Care, Durham VA Medical Center; Sven-Erik Bursell, PhD, Joslin Diabetes Center, Harvard Medical School

Objectives: To compare the effectiveness and cost of using teleophthalmology (TO) versus routine eye exam (EE) for diagnosing diabetic retinopathy and macular edema.

Methods: We conducted the analysis by developing a Markov model. A cohort of 50-year old diabetics entered the model in "good ocular health." In following one-year cycles they remained in this health state, developed proliferative diabetic retinopathy (PDR) or clinically significant macular edema (CSME), or died. If they developed PDR or CSME, they may receive treatment and regain good ocular health, develop blindness, remain alive with PDR or CSME, or die. The intervention subtrees differed by 1) the proportion of diabetic patients screened by EE (0.60-0.83); 2) TO image failure rate (26%); 3) the test characteristics of TO and EE; and 4) adherence to follow-up exam (0.87 for TO and 0.77 for EE).

We derived transition probabilities, intervention test characteristics, health state utilities, and annual cost of blindness from the literature. We derived intervention costs via micro-costing and treatment costs from Medicare reimbursement rates. We applied a 3% discount rate to future costs and effectiveness.

We conducted 10,000 iterations of second-order Monte Carlo simulation of the Markov model to generate results. We also conducted extensive one-way sensitivity analysis to determine which parameters drove the model and the threshold values at which the results could change.

Results: The model estimated a lifetime expected cost of $620 (95% confidence interval (CI) $510-$732) for a patient receiving annual TO screening and $708 (95% CI $495-$968) for a patient receiving annual routine EE. TO patients accrued 9.0 QALYs (95% CI 8.6-9.4 QALYs) and routine EE patients also accrued 9.0 QALYs (95% CI 8.6-9.5). The model was sensitive to five model parameters: 1) EE time, 2) gradable image percentage, 3) proportion of population screened by EE and TO, 4) follow-up adherence rate, and 5) sensitivities of TO and EE.

Conclusion: Teleophthalmology is potentially equivalent to routine eye exam for diagnosing PDR and CSME but can do so at lower cost per patient.

Impact Statement: Teleophthalmology may provide a cost effective solution for improving compliance with VA guidelines that call for annual eye screening for diabetic veterans.

Joslin Diabetes Center Research and Development Status Reports

The above section addressed the research components of this large collaborative effort. In the following section, we summarize key issues and milestones in the technology research and development.

Establish a centralized JVN Telehealth clinical coordination center to facilitate the proposed multicenter clinical trials. Telehealth Clinical study Coordination Center as a module of CDMP to Facilitate proposed clinical trials

The JVN Telehealth clinical coordination center is an integral part of JVN program moving forward in the future and will provide the critical capability of providing a variety of professional services that provide value added to the JVN program as it begins to undertake the proposed rigorous multicenter clinical studies. These services were designed through the clinical coordination center under the direction of Dr. Stephanie Fonda, Dr. Lloyd M. Aiello and Dr. Bursell and provide pathways for direction and testing of various clinical work flow models as well as coordination and facilitation of different JVN related multi-center clinical trials. The expertise and programs provided through the coordination center present a compelling value to the JVN participating sites. The services that were provided are outlined below:

1. Client training on all tools; capture of clinical feedback for software updates; modifications to JVN clinical workflow processes as desired by health professionals using the JVN system.
2. Support for clinical programs development, identifying site-specific program requirements, and clinical pathways and workflows
3. Support for reading center services, establishing and updating certification programs and courses, maintaining performance for image review and reporting services, scheduling timely quality assurance reviews, and providing ongoing consultation services
4. On-going clinical support through resource development, maintaining quality assurance, consultative services, and provision of pre/post-deployment periodic site visits
5. Provide continuing education, both on-site at the JVN Tele-Health Clinical Coordination Center and at remote sites through on site visits or video teleconferencing
6. Coordinate reading centers to provide ongoing certification and re-certification services, for image acquisition specialists, image review specialists, and remote reading centers
7. Coordinate all clinical study activities associated with the clinical coordination center and provide a centralized data repository for the different proposed clinical studies.

Status:

Development of the Study Manager Module in CDMP with the data base established to support storage of study data and the utilities required to access this data for analysis has been completed and code development for anonymization of data, secure messaging, HIPAA compliance, and centralized storage has been completed. The module has been implemented and is being used by clinical study coordinators at the participating sites conducting proposed clinical studies

Clinical validation of the JVN Eye Care computer algorithm for automation of detection of retinal lesions. Determine the sensitivity and specificity and Receiver Operating Characteristics (ROC) of the performance of the algorithm for detecting retinal abnormalities from undilated eye JVN digital video retinal

images compared to dilated eye ophthamological evaluation of retinal images from 35 mm retinal fundus photography.

Status:

The algorithm development has been completed and undergone validation testing. The results of this study will be presented at the Association for Research in Vision and Ophthalmology conference April 24 to 29 2004. Additionally a manuscript has been prepared for submission to SPIEE. This software module will be incorporated in the next JVN version release based on the MS .Net operating system. Algorithm has been reworked with additional improvements to assessment of overall image quality and improved algorithmic detection of retinal features. Currently the new algorithm has undergone training and validation and is currently being tested against a new set of 216 JVN retinal patient studies. Results from this work have been presented at the ATA meeting in 2005 and at the ARVO meeting 2005. This algorithm will be implemented into the JVN version 3 release at the end of December 2005. Due to funding cut backs the work here has become a low priority and currently we are unable to take this forward. ***This work will continue under the new contract at the University of Hawaii***

Clinical validation study for the JVN developed retinal imaging device. Determine the level of agreement in retinopathy diagnosis comparing retinal images taken using the new JVN portable retinal imager and the clinical gold standard of dilated eye ETDRS protocol 35 mm 7 stereo standard field photography.

Status: This study has not been initiated as retinal prototype development was cancelled due to reduction in funding for 2003 to 2007. Some additional work has occurred but is a lower priority. Currently modifications to the prototype now allow full field retinal images to be acquired without portions of retina being occluded by reflections from the lens and cornea. A US patent has been granted for this technology (US Patent # 7,338,167). Examples of retinal images obtained by this prototype are shown below. Currently exploring partnership with a device manufacturer to develop some beta units that can be clinically tested. Images below are retinal images taken with the retinal imaging prototype

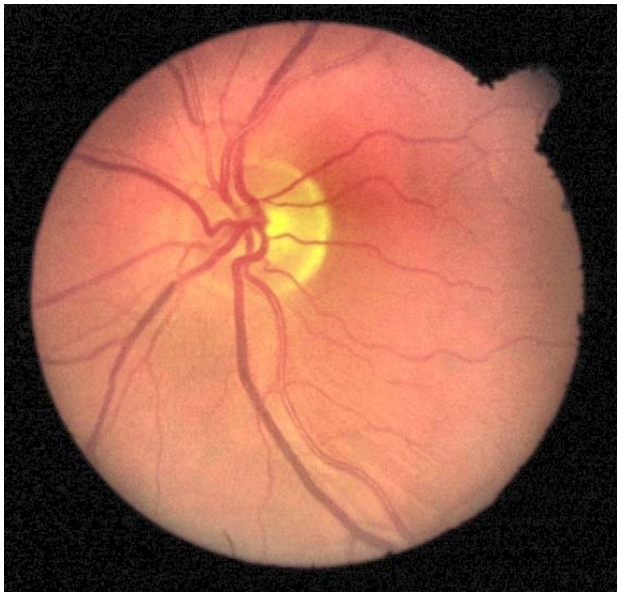


Figure 1: Retinal image obtained from a young old male non-diabetic volunteer

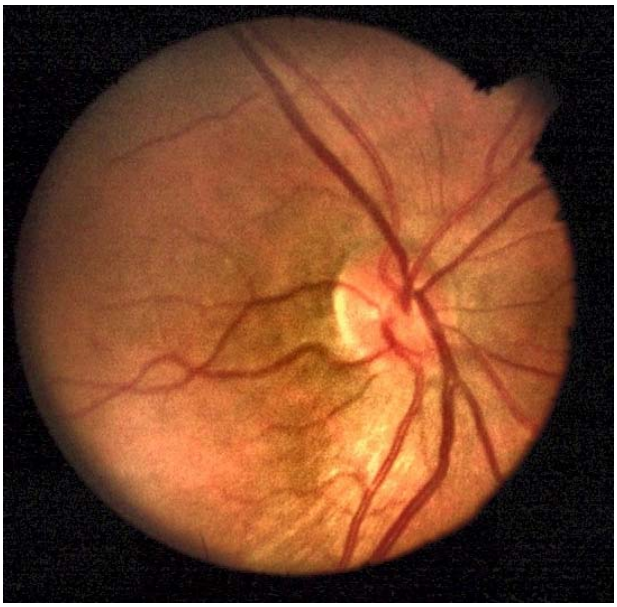


Figure 2. Retinal image obtained from a 60 year normal non-diabetic male volunteer

Automation of the retinal image taking process using the JVN developed retinal imaging device. Development of scanning technology that will automate imaging and simultaneous stereo acquisition of different regions of the retina determined to be essential for accurate diagnosis of diabetic retinopathy.

Status: This component has not been initiated due to funding reductions in 2003 to 2007. Once the retinal imaging device can be produced we will conduct the necessary clinical validation study.

Software Application for 3-Dimensional Visualization of the Retina

Optic Nerve Head Mapping from Stereo Pairs

In lieu of the above automation process we have been investigating utilization of image analysis techniques to provide three dimensional mappings of the retina. These would be of value to provide an indication of relative elevation in the macula as an indication of risk for macula edema a sight threatening process or development of optic disc changes potentially associated with the development of glaucoma.

The figures below illustrate the work completed in this area.

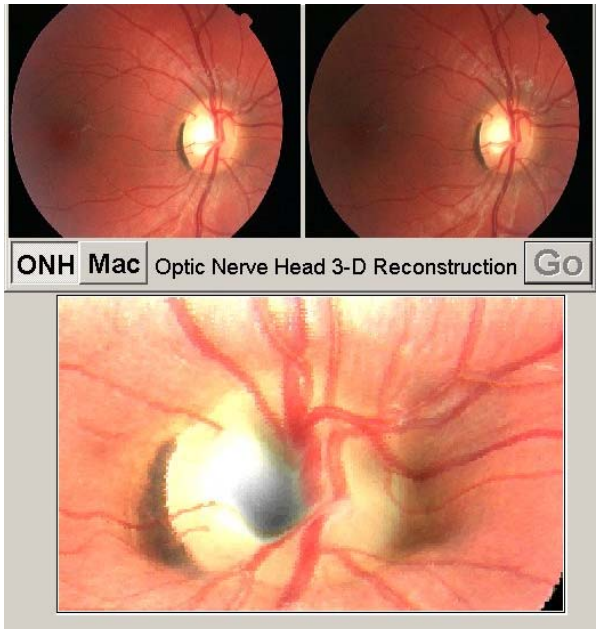


Figure 1. Optic Nerve 3-Dimensional reconstruction patient with a normal optic disc

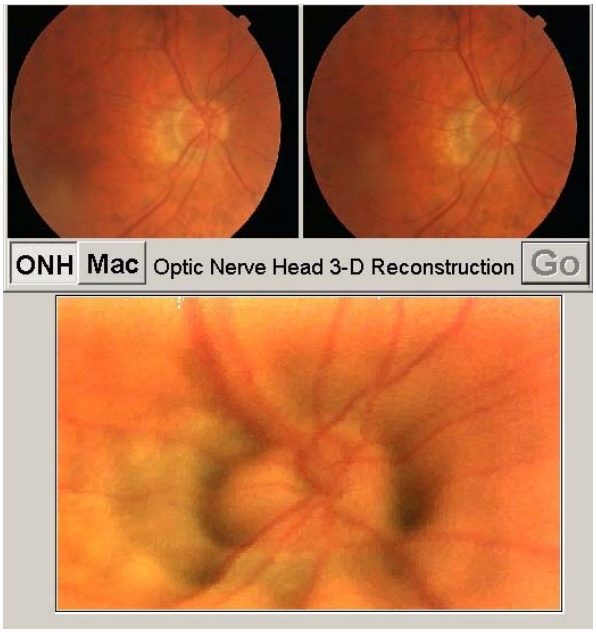


Figure 2. Optic Nerve 3-Dimensional for a for a reconstruction for a patient with Papilledema

Status: Due to funding reductions we have been unable to fund and perform the work proposed here

Migration of JVN Eye Care module to Microsoft .Net operating platform. Development of a software enhancement that will allow improvement in performance and reduce costs of technological support.

Status: The software development for the JVN image acquisition application has been completed. Below is a summary of work performed:

JVN IMAGER

JVN 4.0 Imager is an image acquisition product for capturing retina images based on the previous product JVN V3.0 (IA). MegaVision's digital camera back has been integrated in JVN V4.0 Imager. We have completed the following new features and enhancements:

- Add MegaVision's RIC Digital Camera to the product
- Allow to save original raw image data
- Re-program the product with Microsoft.NET technology to eliminate the troublesome product architecture generated by an outsourcing company. With the new Microsoft.NET technology, the architecture and product reliability will be dramatically improved.
- Resolve defects reported from previous releases.
- Improve user interfaces and product performance.

- Improve Modality Work List search engine.
- Support the compatibility of existing image acquisition devices

JVN SERVER

JVN 4.0 Server, a subset of the CDMP server, is an image and information management server that provides permanent storage capabilities of ophthalmic image and related information. Its function is mainly to provide "on-demand" distribution of diagnostic images of ophthalmic photography and related clinical reports of diagnosis, and also to automate permanent storage with virtually unlimited storage capacity. It is a service-provider oriented server that will be normally located in Joslin Diabetes Center, or perhaps other centralized hospital/clinic locations, if necessary. Furthermore, it provides features that contribute to the enhanced workflow of ophthalmologists and other ophthalmologic clinicians. It also provides information management features to those administrators who perform daily clinical and technical supports. The JVN Server consists of two major components: JVN DICOM Server and JVN Reader that leverages CDMP data monitoring and reporting capabilities. We have completed following major features:

DICOM Server

DICOM exists as the universal glue to connect JVN Server with JVN Image Acquisition and potentially any external 3rd Party DICOM Systems. This is the interface over which JVN Server will receive images, structure reports, and HIS scheduling events. DICOM is also used to transmit images and structure reports out to other systems, but only when the "On-Demand" interface is not applicable.

The "On-Demand" Interface is a proprietary interface for the transmission of the images and managing of the workflow related to those images. The "On-Demand" Interface allows studies to be locked to a particular user, and the status of the study to be altered accordingly. This interface also offers a faster mechanism for the transmission of images to the requesting viewing workstation.

- Support DICOM XC and OP images
- Support DICOM Structure Report – SR objects
- Support DICOM Storage SCP
- Support DICOM Modality Worklist Provider SCP
- Support DICOM Storage Commitment SCP

2. HIS/HL7
   - Support HL/7 message listening and parsing functions
3. Storage
   - Support for RAID Level 5 or higher storage configurations
   - Support for SAN/NAS configurations for permanent storage as integrated long-term storage
   - Support for storing data into Oracle database
   - Support for storing images and reports to the file system
4. Image Compression
   - Support for standard JPEG2000 color compression and decompression

5. UI (User Interface)
   - Web Server with Microsoft ASP.NET technology
   - Support Web-based clinical user interfaces (see Reporter features)
   - Support Web-based clinical reporting functionality (see Reporter features)
   - Support Web-based administrative reporting functionality for clinical services
   - Support Web-based administrative functionality for technical services
   - Support a proprietary interface to provide "On-Demand" style functionality to JVN Reader.

6. Reporter

- Support a server application integrated with the JVN Reader client application
- Support study worklist display and filtering
- Support the entry of clinical findings and other patient data
- Support algorithms for the determination of potential eye diagnoses and risks
- Support review and distribution of completed JVN study reports

JVN READER

JVN Reader V4.0 is a Microsoft Windows based application that leverages CDMP for its reporting and storage functionality. This application has been designed with a large number of features to meet the needs of ophthalmic photography image display and diagnosis. We have completed following major features:

- Worklist and Clinical Findings interfaces – will access JVN Reporter and provide end users with patient/study worklist, clinical findings templates, and clinical reports templates. By linking to JVN reporter and JVN DICOM server, the interfaces will also provide a mechanism to download patient study related images for further diagnosis.
- Diagnostic Display – Diagnostic image display is a major software component that consists of a set of standard image process tools and a set of advanced image process tools. Diagnostic images are displayed on a thumbnail monitor and primary viewport monitor. Diagnosis can be done through using the thumbnail display and primary display, combined with the image process and manipulation tools.

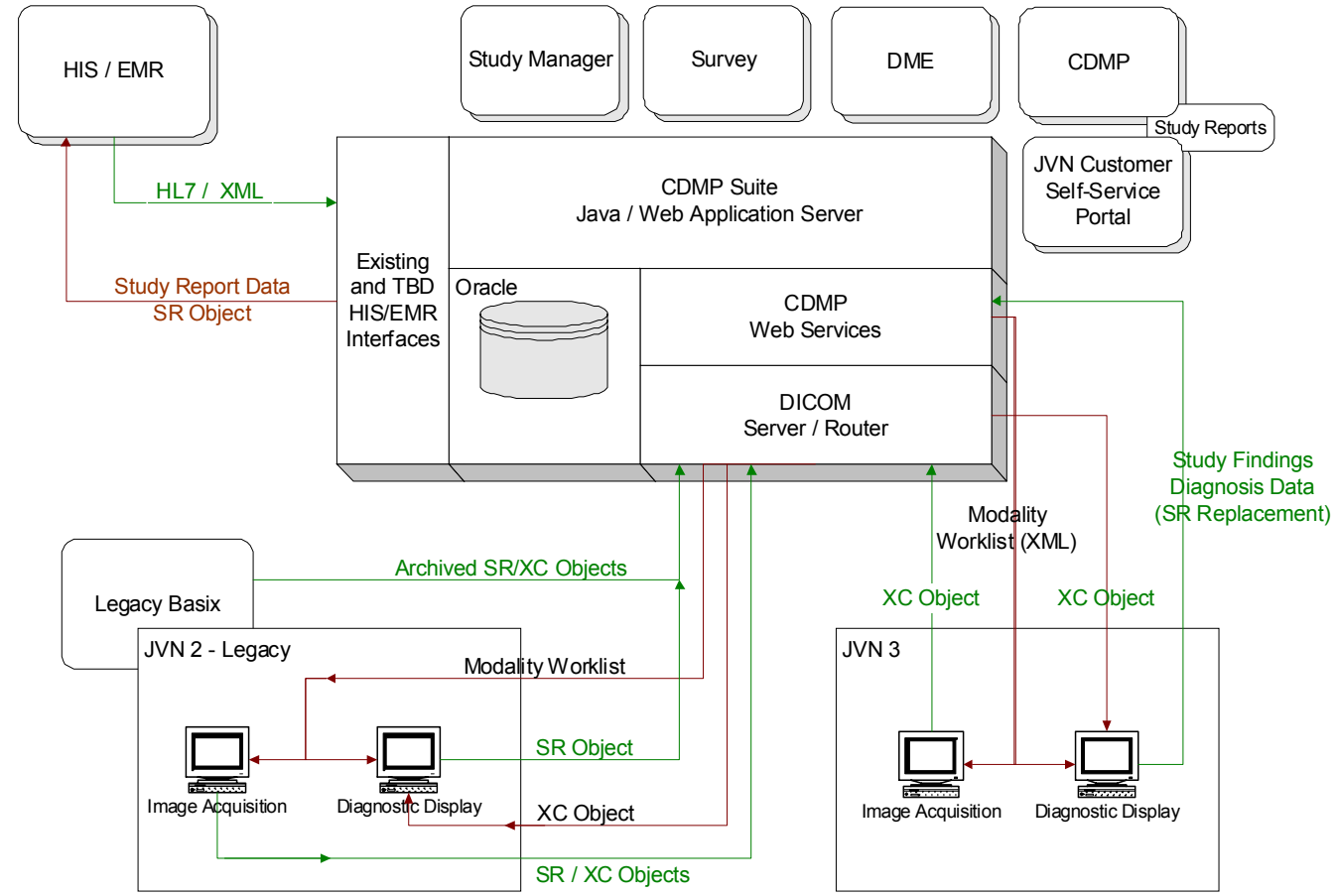
Reader-Server collaboration engine - JVN Reader uses the engine to communicate with JVN server where the study images are physically stored. This engine will triangulate JVN Reporter-Sever-Reader three parties to make web HTTP linking, image downloading and event notifications.

Department of Defense Integration Requirement.

Because of the introduction of CHCS II in the WRAMC Network we have also initiated an effort to accelerate the development of the JVN diagnostic display work station such that the CDMP and JVN eye care are a single application that can be embedded directly into CHCS II. This effort involves the integration of JVN diagnostic display into the CDMP application. It requires the development of a DICOM viewer integrated as a module in CDMP and leverages all the reporting capabilities of CDMP to generate diagnostic findings, clinical, diagnosis and clinical performance reporting. Included in this design will also be the ability to provide assessments and diagnosis for general ophthalmology applications. The advantage here is that the whole application exists on an open architecture leveraging the web based technology used for CDMP and no longer requires reliance on Agfa as a third party vendor for the PACS system. This is a necessity as Agfa has been no responsive to our support requests over the past 18 months despite the fact that we have paid them $30,000 per year for support of our application. The Figure below illustrates the high level architecture for the proposed solution.

We have completed the functional requirements definition portion of the project, the technical design portion of the effort, the software coding and the testing and implementation.

Proposed JVN - CDMP Architecture



CDMP Development

Overall, we have been able to capitalize on our original mission: Create a patient-centric diabetes treatment application that fills the gaps in standard disease management software and empowers patients to become good self-managers through timely, accurate information and solid, collaborative relationships with their care providers. Support those providers with a number of clinical decision support tools and embedded education.

We are fortunate to be working with our original development team, using a strict system development methodology, conscious of the need for quality and documentation.

To review, the CDMP is a two-part application developed for medical centers and clinics.

The first part of the application -- the CDMP Core (the Provider Portal) -- is a web-based, secure, one-stop, customizable, non-proprietary clinical tool that considers the whole patient and embraces Wagner's components for patient-centered chronic care. CDMP's primary users are

- Care managers who facilitate interactions between patients
- CareTeam (physicians, nurses, educators, exercise physiologists, nutritionists, and behavioral clinicians)
- Providers without specialization in diabetes

The second part of the application -- the Patient Portal (currently called DME) -- is also web-based and secure. It is a set of tools for self-management and communication that provides:

- A current health profile that reflects CDMP data in patient language
- The ability to upload, review, and share (with a designated provider) personal health data from one or more monitoring devices

- An evolving patient-centered collection of health histories, articles, plans and suggestions designed for that patient and his/her support system.

Functionality Summary:

- **Reporting Module** - CDMP is establishing a set of standard reports to be embedded and, therefore, available to every user. The first group of reports will fulfill DQIP, HEDIS and other certification criteria. Later reports will encompass more patient, provider, and site performance.
- **Study Manager** - Developed to aid performance reporting and outcomes, this application has generated much interest in the research and provider communities because it lays out the process of capturing that information in a series of successive steps.
- **Nutrition Module** - Bi-level nutrition assessment tools, the first for diabetes generalists to assess patients for the amount of control they have over the food issues in their lives. The second assessment is for CDEs and nutritionists to assess more subtle financial, emotional and lifestyle issues while looking at food choices and control.

  We have begun the process of folding into the module an application that analyzes the selected components of foods and, with a nutrition profile of a patient, evaluates the balance of the patient's meals and makes suggestions that include essential nutrients and foods.

- **Patient Portal** - DME Everywhere, our portal, is evolving with rigorous use by the VA. We have made significant changes in language level and visual clarity in the past six months. The portal allows the patient access to a current CarePlan, health profile with underlying clinical guidelines, and vetted web and other media-based materials for a Learning Plan. The following is a partial list of benefits for the patient:
  - Uploading and trending reports for self-monitoring information - BG, BP and other monitors
  - Self-management advice
  - Wellbeing and coping surveys
  - Lab test results annotated with patient language guidelines
  - Graphical indicators of Vitals - A1c, weight, BP
  - Graphical Health Profile - With risk level (red, yellow, green), assessment taken from Risk Profile along with "How to Lower Risk" *short* narrative in patient-friendly terms
  - Patient Take-Home version of CarePlan - same as the patient is given at a visit
  - Mechanisms to communicate securely with CareTeam on routine issues or problems, such as adjustments to self-management plan, resource information from their care team, non-urgent questions
- **CarePlan** - Significantly updated dynamic care planning is done and adjusted with the patient. The plan addresses our three targets - physical wellness, lifestyle self- management, and psycho-social health - while considering the issues of provider time, data-entry redundancy and plain language. CarePlans are easily updated and created.
- **Survey Architecture** - Our robust architecture has allowed us to add surveys of all types to the core application to assess for depression, willingness to work on problem areas, and education needs.

Training

With a growing user base and more and more requests for demos, we have developed both

- demo systems with scripts that take the user through the core application, DME and the newer assessments and
- training materials that familiarize new users first, with the basic features - Alerts and Reminders, the Patient Snapshot, the Risk Profile, and CarePlanning - then gradually add in nuance and greater detail that optimize the application.

CDMP Clinical Data Warehouse - CDMP was designed to collect and maintain large amounts of data and a structure able to

- de-identify that data,
- perform structured queries,
- provide studies support, and
- develop predictive models.

Expert Reviews
The CDMP and its behavioral survey tool, *Understanding Your Diabetes,* have undergone expert reviews from American Institutes for Research. It is currently undergoing usability tests with the same organization.

Our own semi-annual reviews with the development consortium have produced pragmatic and valuable insights leading to more depth in the tools and greater interest from potential users.

Other CDMP Modules and Studies
Developing new modules to expand the capabilities of the application, and working group meetings to confirm functionality and identify additional functional enhancements.

Module Development and validation of Learning Level Assessment and Readiness to Learn tools for the JVN Telehealth CDMP application

This effort was identified as the first phase in developing a tool for patient knowledge assessment in the CDMP. The CDMP identified learning level assessment and readiness to learn as critical capabilities for enhancement of the CDMP application. It was recognized that there were only a few studies that addressed these issues and that the ability to perform rigorous studies to assess learning levels was of high value for this program.

The only validated tool for learning level assessment is the Rapid Estimate of Adult Literacy in Medicine (REALM) (1). This tool was developed as a rapid screening device to assist physicians in identifying patients with limited reading skills and in estimating patient reading levels. The results from this study suggest that the use of REAL appears to be a practical instrument for estimating patient literacy in the arenas of primary care, patient education and medical research. Another study used the Wide Range Achievement Test (WRAT) for measuring reading ability and spelling (2). Study results found that the better the ability to read and spell the better the accuracy of recall for food intake.

The limited studies currently available that address this issue provide the rationale and value for the development of a Learning Level Assessment tool for the CDMP. Concomitant with learning level assessment there also needs to be the ability to assess the patient's readiness to learn. Clearly if the patient has no interest in learning then the level of learning ability will be of little value.

The CDMP working group will develop a learning assessment tool based on the current validated measures and the available expertise within this group in the behavioral sciences will provide a valuable tool for assessing the patient' willingness to learn. This effort will be unique and will provide a significant advance in diabetes behavior modification.

Upon completion of this tool, it will need to be validated in a study comparable to that designed for the BAT above.

Status: Development of the appropriate tools that meet the different user requirements have been completed.

Usability Study. The Usability study of the CDMP application has been completed and the results were presented at the recent American Telemedicine Association Conference in San Diego. A number of proposed modifications to CDMP were identified from this study and are enumerated below. All modification have been incorporated into the CDMP application.

1. Patient Menu
    a. Change Patient Home menu option to Patient Snapshot. Make this the default page when viewing a patient. Add a menu option for Alerts/Reminders. (multiple changes will be made to inform the user of new alerts/reminders. See below under snapshot).
    b. Add menu option under Patient Snapshot for Alerts/Reminders. **Status:** Not Done, Patient Home link still on patient menu to go to alerts/reminders
    c. Change Education and Education Assessment menu options.
        i. Change the word Assessment to Evaluation.

ii. Change/regroup menu options related to Education and Education Assessment.

Change From this	To this…
Education Ed Assessment - New - History	Education - Assigned - Add/Edit Evaluation - Evaluation History

d. In places where menu options just expand the menu when clicked, we will create a page that displays the submenu options. For example, when the user clicks Clinical, the menu will expand as it does now, but also display a page listing the menu options underneath Clinical. Each menu option will be listed with a description of that page. The menu options can be clicked on that page or in the menu.

2. Snapshot – will be done in conjunction with 1 patient menu changes
   a. Enhance information related to alerts in top left panel to make new alerts more clear.
   b. Add information in top left panel about reminders due.
   c. Add "alert message" in header similar to home page notification of new messages or SMBG or SMBP data to notify user of new alerts. **Status:** It was determined that this was not necessary…alert is on Care Team Home not on patient level, future enhancement to add patient level alerts
   d. Add printer-friendly functionality.
3. Care Plan
   a. Action Items/Reminders Tab
      i. Change Action Item Tab name to Reminders. Status: Implemented in CDMP
      ii. Change "Close" to "Done" (or "Completed" – see above).
      iii. Move Add Action Item Button on Reminder tab to top of tab so it is easily seen.
      iv. In Assigned To drop down – change the patient entry to the actual patient's name.
      v. Create Action Item/Reminder Categories for organizational purposes.
   b. Save/Cancel button – the save/cancel button should always be visible on this page – either add to bottom or modify page so top buttons are always visible.
   c. Close Process
      i. Actual End Date goes away
      ii. Care Plan automatically closes when planned end date passes [close checkbox is used]
      iii. When user clicks add/edit
         1. if a care plan exists and is open, display current care plan
         2. if care plan exists, but is closed, a new blank care plan will be created
            a. Future versions will allow you to copy the old to the new.
         3. If no care plan exists, create a blank care plan.
   d. Remove the Physical Tab
4. Alerts
   a. Modify the Alert Close Process [enhancement was to add buttons to allow the user to add an action and close the alert in one step]
      i. Change "Close" to "Delete"
      ii. No Action Item is required.
      iii. When Delete is selected, display a popup confirmation message to make sure they really want to delete the alerts.
   b. Add a mouse over on the filtering to explain what it does. [changed filter link to explicit "ON" and "OFF" option buttons]
5. Education Assessment (Now Evaluation)
   a. Modify text on page to reflect change to "Evaluation"
   b. Change method used to select subcategories.
      i. Remove existing drop down, link, and display
      ii. Add one link "Add/Edit Target Areas", when clicked
         1. DHTML list of available options are displayed
         2. User can select multiple by selecting checkboxes.
         3. user clicks Save/Cancel
         4. DHTML window closes
      iii. Selected Target Areas are display in list on right hand side

1. Next to each item, display a delete icon. If clicked, delete the item. No confirmation required.

6. Reminders
    a. Change “Close” to “Done”.
        i. Open Item: Is “done” the best? What about “completed”?
    b. Drop Reminder Category.
    c. Display assigned by as right most column – this is the created by column
    d. When viewing Patient reminders – remove ability to filter – always display all reminders
7. Miscellaneous
    a. On all panels where data is sorted.
        i. Display an arrow next to the column header indicating the direction the data is sorted.
        ii. This sort indicator should be displayed on initial page retrieval.
    b. Update Data Changed Message – “Press OK to discard changes and leave this page. Press Cancel to stay on the current page.”
    c. JVN Eye Diagram – add text “Click on R/L links or image list to see eye images”
    d. Graphs – on y-axis – rotate dates so they are easier to read – should be displayed horizontally.
    e. Clinical Data Listings (Labs, Medications, Procedures, Diagnoses)
        i. Add alphabet across top, clicking on letter filters list based on the letter selected.
        ii. Have “all” option to return to base – have tool tip when user mouses over all to explain this.

Home Monitoring Module.
This has involved developing a collaboarative partnership with iMetrikus

Partnership with iMetrikus. As the patient portal began to be used by more and more patients to track critical aspects of their health and upload their meter data, we began to see an increase in the time our technical team and Estenda Solutions spent interpreting data, and documenting and supervising operating procedures for a variety of glucose meters. In order to efficiently provide functionality for increasing numbers of physiological home monitoring devices CDMP development initiated a partnership with iMetrikus, who provide a large number of device adapters and a universal data interface to the CDMP data server, both allowed us to branch out to other disease states and types of devices and frees the technical development team to focus on other more critical CDMP development efforts.

iMetrikus currently supports some 30 devices – blood glucose, blood pressure, weight scales, and oximeters, with more in the pipeline every day. The MetrikLink adapters convert the data into a single format for delivery to the MediCompass hub. CDMP takes the data handoff directly. iMetrikus is currently working with us to support several devices types within the same clinical program.

Status:
The iMetrikus CDMP interface has been developed, tested, and implemented and we anticipate starting a proof of concept study involving 20 patients with our partners in the Indian Health Service using the iMetrikus solution for home monitoring of blood glucose, weight and blood pressure.

Nutrition Module. A CDMP working group has put together several basic tenets of meal planning and nutrition information for patients and providers and is now working to find supporting web-based materials available for online work and/or printing for handouts. The CDMP web-based education list now includes most of the vetted sites the working group found valuable. The working group is also looking to find a new way to present this information to patients with limited general and health literacy.

Status: The Nutrition module to be used in conjunction with the 2 nutrition surveys developed for CDMP has been completed. Further the library of nutritional resources that can be used by care managers has been significantly expanded.

Medications Module. Medications are an increasingly important topic in the discourse on patient safety and personal health records. The CDMP Consortium, therefore, has determined that it is necessary to develop a state-of-the-art medications module.
Discussions on medications have led to several iterations for Consortium consideration. Questions were:

- Do we present both disease state-specific – diabetes, in this instance - meds related and general meds?
- About off the shelf medications and supplements, should they be included?
- How much real estate is available for medication categories?
- How far back should the medications tracking go for presentation?
- If EMR doesn't include all meds, how are they added?
- If EMR doesn't include a pharmacy module, how to track filled scripts?
- How to consider medication or supplement self-reports?

Status: . This module has been completed and below is the screen illustrating the form for medication presentation in CDMP.

Date	Name	Dosage	Frequency	Last Filled	Notes	
06/01/2006	METFORMIN HCL	1000 mg	qd		This is a test	
05/13/2006	ACTOS	30	q am			
04/07/2006	GLIPIZIDE	5	2 Times per Day	04/07/2006		
03/09/2006	A.S.A.	1	as directed	03/09/2006		
07/07/2005	ACETAMINOPHEN	20-12.5MG	bid			
04/17/2005	PRINZIDE	20-12.5MG	bid			
09/13/2004	TERAZOSIN HCL	2MG	q hs			
09/13/2004	SYNTHROID	125MCG	qd			
09/13/2004	HUMALOG	100U/ML	as directed			
09/13/2004	ONE TOUCH ULTRA - STRIPS	STRIPS	as directed			
09/13/2004	BD Ultra-Fine - Syringes	29G 1CC	as directed			
09/13/2004	HUMULIN N	100U/ML	as directed			
09/13/2004	ZESTORETIC	20-12.5MG	qd			
09/13/2004	FUROSEMIDE	40MG	q am			
06/13/2004	ZESTORETIC	20-12.5MG	qd			
06/05/2004	ONE TOUCH ULTRA SOFT - LANCETS	LANCET	prn			
06/05/2004	ONE TOUCH ULTRA - STRIPS	STRIPS	N/A			
06/05/2004	ZESTRIL	20MG	bid			
06/05/2004	FUROSEMIDE	40MG	q am			
06/05/2004	ONE TOUCH ULTRA - STRIPS	STRIPS	as directed			
06/05/2004	SYNTHROID	125MCG	qd			
06/05/2004	TERAZOSIN HCL	2MG	q hs			
01/03/2003	ONE TOUCH PENLET LANCET	LANCET	as directed			
01/03/2003	ONE TOUCH MONITORING - STRIPS	STRIPS	as directed			
01/03/2003	BD Ultra-Fine - Syringes	29G 1CC	as directed			
01/03/2003	HUMULIN R	100U/ML	as directed			
01/03/2003	HUMULIN N	100U/ML	as directed			
01/03/2003	SYNTHROID	125MCG	qd			
01/03/2003	FUROSEMIDE	40MG	q am			
01/03/2003	ZESTRIL	20MG	bid			

Mental Health Module. The Consortium recognizes the important, reciprocal relationship between diabetes and poor affective functioning, such as depression. Care management tools may mitigate the relationship. See, for example, the attached paper authored by Fonda and colleagues and currently

under review, "The Relationship of Internet-based Care Management and Changes in Glycemic Control to Depressive Symptoms and Diabetes-Related Distress." Thus, the Consortium is deepening the mental assessment and decision-support tools within the CDMP. The goal of these tools will be to identify depression and giving providers guidelines to handle the outcome. How to refer, who are first line providers, etc. are clinic specific issues that affect workflow. As with the basic nutrition assessment tool, such tools will include a scoring script – "If this, then this." to facilitate mental health care delivery – often a presence with patients already coping with diabetes, CHF, etc.

Status: The work here was deemed low priority and discontinued because of funding reductions. However, the work here will continue under the contract with Hawaii and will specifically focus on issues the affect patient willingness to change with respect to lifestyle and behavior modifications

Training tools.

Our CDMP Usability work with AIR and direct work with CDMP users changed some of our approach to training CDMP users. Traditional training involves taking the user logically through the application and covers keystrokes and trouble shooting. FAQs, and online Help provide local support. We created a new way to use CDMP. Functions are grouped as they are often used – at least in the beginning – as

- Reference tools
- Assessment tools
- Communications tools
- Collaboration tools
- Survey tools

Some of our current CDMP users find this annotated-screen, paper-based, spiral-bound booklet sits at the computer with them. They can stay focused on the work they are doing without having to open other windows to find help.

Status: The training modules have been completed and are available as part of the CDMP application

CDMP Summit Summary.

The CDMP Consortium – comprised of Joslin, JVN TeleHealth, DOD, VA, IHS, CDC, CHCs, and specialized academic researchers – meets twice a year with the overall goal to share technical, clinical, and behavioral updates to the CDMP Core application, JVN imaging and reporting tool, the patient portal, survey tools, and the study management tool. Most of our members are part of ongoing studies and working groups. This meeting allows us to share research, and related software and hardware development coming out of our clinical and behavioral work. We call these meetings "Summits".

Each Summit we try to include speakers with complementary and related research, products and programs. Moving the Summit to different locations gives us access to local clinics and clinicians who do what we do. They are always receptive to sharing some of their work with us resulting in productive question and answer sessions.

Last winter's 2005 Summit, we heard from several researchers (several of whom are longstanding members of the Consortium) who are developing tools that may be appropriate for incorporation into the CDMP. Specifically, we heard from Kate Lorig, founder and director of the Patient Education Research Center at Stanford University. She has developed peer education programs that let patients with similar needs talk to each other, led by a patient trained in the Center's methodology. Another Stanford researcher, Mary Goldstein, presented her work with hypertension. She has developed a decision matrix to guide clinicians through the web of HTN treatment. Dr Dale Vincent (a member of the Hawaii team) presented on the value of group visits and how CDMP could be used to facilitate this process. Dr. Jamie Rosenzweig from Joslin is working on a Doctor's Quality Project looking at currently accepted diabetes care measures, where they come from, about the National Diabetes Quality Improvement Alliance standards, and public reporting.

This summer's 2006 Summit offered a wide spectrum of disease management topics and experiences. To summarize, the VA investigators presented their experiences using the CDMP in their research study described above. Dr. Lloyd M. Aiello and Marc Van Marter, a senior JVN developer, presented what's new and forthcoming with the JVN eye care program. Dr. Vigersky presented on the decision matrix of a new tool

providing clinical decision support tool for health care practitioners who care for people with diabetes. Additionally, Dr. Susan Oliverio, an internist on the staff of the Neighborhood Health Plan in Boston, presented her work on an interactive program called “Thumbs Up for Healthy Choices” for kids and adolescents. Dr. Stephanie Fonda and Judy Phillips presented aspects of the digital photography and nutrition study summarized above. Dr. Dale Vincent led a discussion about the use of cell phones, specifically SMS text messaging, as a particularly effective self-management tool. Next, Dr. Christine Paulsen, from the American Institutes of Research (AIR), presented on expert reviews and usability testing. Dr. Garry Welch presented on his experiences using CDMP for bariatric surgery, and his involvement in the Hispanic initiative in Springfield. Lastly, Kevin Nickels, CEO of Celleration presented on their medical product dealing with the use of specialized ultrasound technology as a wound healing mechanism.

Status: The biannual summit meetings were discontinued due to funding reductions.

Eye Care Application Development at Joslin Diabetes Center

There have been 2 major drivers that have dictated the technical development of the JVN Eye Care component of this project as outlined below:

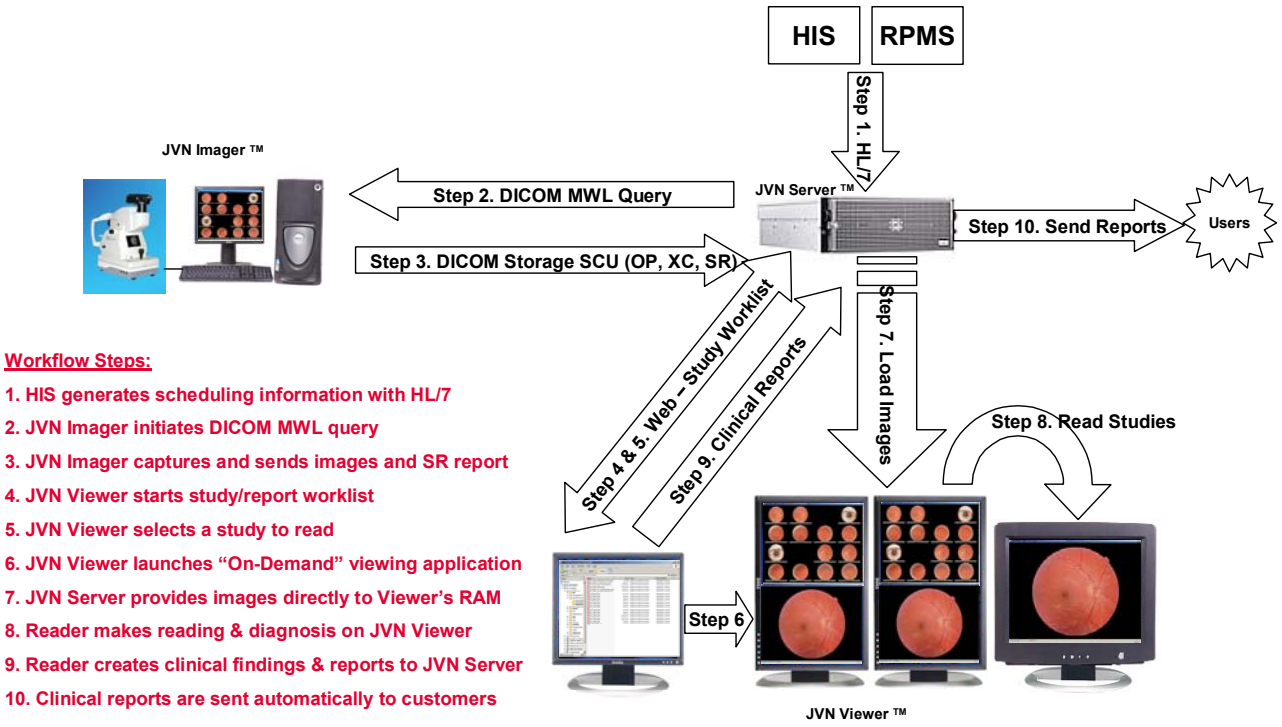
1. The requirement to integrate the JVN system into AHLTA required an acceleration of the integration of the JVN Eye Care application as a module of the CDMP application. The aim here was to provide a single application that encompassed all our development work both in eye care and diabetes care into a single application that was ready for integration into AHLTA. This critical step has been accomplished together with added functionality into JVN Eye Care with the release of the next generation of JVN software (JVN 4.0)
2. With emerging technology the current JVN eye care analog video cameras were no longer being produced which required a development effort to define the specifications for a digital non-mydriatic retinal fundus imaging camera that conformed to the JVN specifications for low light level imaging. The discovery process resulted in a partnership with MegaVision to develop the required retinal imaging camera (RIC)

Status:

Successfully implemented CDMP based new clinic finding and reporting engine, coupled with centralized data management system. The new CDMP reporting engine automates the process of reporting clinical diagnosis and findings.

Successfully implemented the new generation of diagnostic reading system for diabetic retinopathy. A schematic of the architecture is illustrated in the Figure below. Many important features have been implemented, including integrated image reading and reporting functionality. The dynamic raw image re-rending based on fundus color, gamma enhancement, and window color balance has been proven to significantly improve the efficiency and accuracy of clinical diagnosis. See schematic of system and workflow in Figure below. The new system is currently operational at all participating sites Hawaii community health centers, Joslin Diabetes Center, Walter Reed Army Medical Center, Indian Health Service program, and additionally at Lackland AirForce Base/Willford Hall.

- JVN Imager ™, Server ™, & Reader ™ – All Together



Workflow Steps:

1. HIS generates scheduling information with HL/7
2. JVN Imager initiates DICOM MWL query
3. JVN Imager captures and sends images and SR report
4. JVN Viewer starts study/report worklist
5. JVN Viewer selects a study to read
6. JVN Viewer launches "On-Demand" viewing application
7. JVN Server provides images directly to Viewer's RAM
8. Reader makes reading & diagnosis on JVN Viewer
9. Reader creates clinical findings & reports to JVN Server
10. Clinical reports are sent automatically to customers

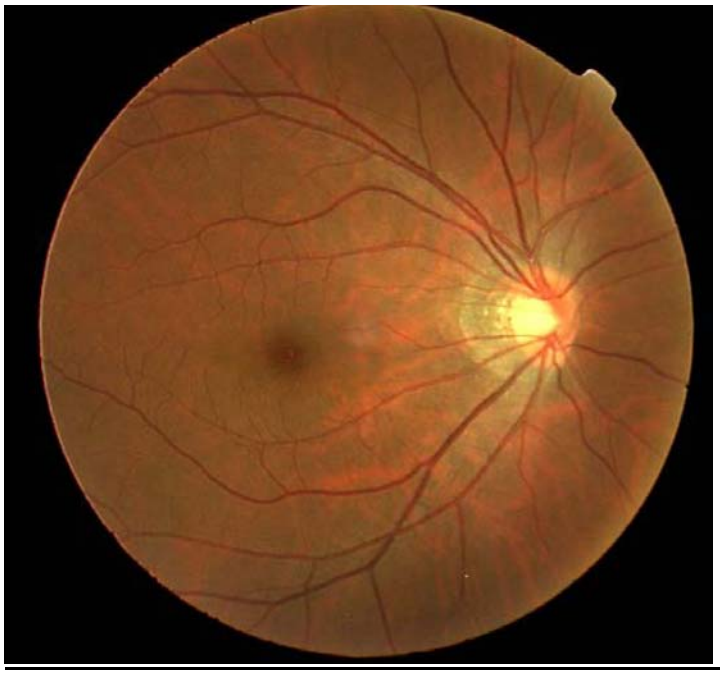
Successfully accomplished MegaVision camera research. We made the breakthrough of discovering how to acquire digital non-mydriatic images under lower or limited flash light. This discovery helped to improve the quality of ophthalmology images in very significant way. Through the raw images acquired by MegaVision camera, we are able to render or re-render images in many different ways, and in preliminary testing ophthalmologists using the system have noted pathologies that were not evident using the older JVN eye care system. We are currently investigating additional methodologies to improve image quality from this camera system.

Successfully accomplished the research of image deconvolution. Many patient/studies have been tested through the prototype of deconvolution algorithm. The data has indicated that the deconvolved images can dramatically improve the image quality and make clinical significance of retinal images more predominant, especially for those studies captured through MegaVision camera. The Figures A to F below illustrate images obtained from the same patient using the same exposure settings using the older analog imaging camera, the new digital MegaVision imaging camera and application of the deconvolution algorithm on the egaVision images.

By implementing all above projects, the clinical program has been improved and progressed dramatically as well. Since the image quality has been improved, the image pattern recognition and lesion detection are more achievable, which in turn will automate the diagnostic process and treatment plans. For this purpose, we have started the research of artificial intelligence for implementing a self-learning engine and eventually creating automated clinical treatment plan.

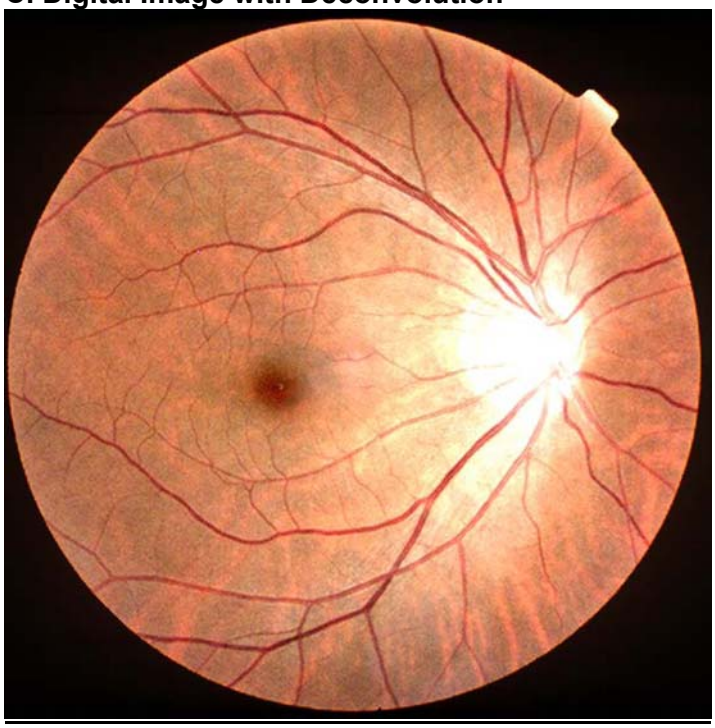
Figures Showing Retinal Image Comparisons using old analog retinal imaging video camera, new digital MegaVision retinal imaging camera and new Retinal Image deconvolution algorithm applied to MegaVision derived images.

A. Analog Retinal Image



B. Digital Image (MegaVision)

C. Digital Image with Deconvolution



D. Analog Retinal Image

E. Digital Image (MegaVision)

F. Digital Image with Deconvolution

Telehealth Program Development (Eye Care and Diabetes Care,JVN/CDMP): Estenda Solutions.
JVN/CDMP Development: Estenda Solutions.

The Comprehensive Diabetes Management Program (CDMP) software solution was significantly enhanced during the 2005-2007 reporting period. CDMP is comprised of five independent software systems that share a common integrated technical architecture. While each of the five components received enhancements over the period, the most significant modifications were made to the Clinical and tele-opthamology applications. In addition to the progress summarized in this section, Estenda Solutions played a critical role in the support of

CDMP for the Usability Study described above as well as rapidly implementing some of the critical modifications identified from this study.

Routine maintenance and enhancement
During the reporting period the Estenda team developed two major versions of the software culminating in the now current version 5.0. Over 175 miscellaneous updates were made as the team addressed user feedback issues across the suite.

Ongoing research support
During this reporting period the Estenda technical team supported live clinical trials conducted at the Boston VA, Joslin Diabetes Center, Walter Reed Army medical center, and University of Hawaii. To accommodate various technology restrictions the team was able to implement CDMP's study management module on several unique platforms including dated laptop technology. The team provided significant study manger design consulting for 3 major WRAMC research projects. The team also assisted principal investigators with access, formatting and analysis of the resulting study data, including analysis for two posters presented at the ATA 2007 annual meeting.

Ongoing implementation support
Modules from the CDMP suite are currently installed at a variety of locations both as part and in addition sites collaborating on this grant. During the reporting period the technical team support installations at: Joslin Diabetes Center; the Boston VA; Walter Reed Army Medical Center; 4 Hawaii based community health centers.

Clinical application
The clinical application underwent significant revision when incorporating functional changes resulting from the independent CDMP usability study conducted by the American Institutes of Research (AIR). Changes were made to key areas such as patient and population alert filtering, care planning. Various findings from the AIR study are included below:

Positive Findings

1. Testers were enthusiastic about the layout of the application, the types of data available on the application's clinical pages, and the application's ability to share patient data among team members.
2. Testers were able to successfully complete tasks that required them to locate existing clinical data for a specific patient.
3. Testers found it easy to read and understand the patient-specific clinical pages.
4. Testers wanted and expected the ability to customize the CDMP for their own use. This is a positive finding as the application was designed for such customization. It will be customized at each site that uses it at the time of implementation.
5. Testers did not quickly grasp all concepts (i.e., the Care Plan, Alerts, Reminders and some CDMP-specific rating scales). Given testers received only a brief training, it remains to be determined whether full training in the application would increase speed of understanding.

Findings Suggesting Areas for Improvement

1. Testers' presuppositions about what the application could do were not always congruent with the application's functionality. This suggested concrete ways that we might refine the application and/or develop training materials.
2. Testers thought certain lists (such as "Action Items" for patients and care managers) were in not in intuitive order.
3. Testers thought that drop-down menus were not an appropriate tool for items where they wanted to make more than one choice.
4. Testers thought error messages should be easier to read.
5. Testers thought that items unique to the CDMP (e.g., ratings scales) should be explained clearly so that even long-time users of the application may interpret the information correctly.

New Implementations
Under separate funding the CDMP suite was installed at Lackland Air Force Base, The National Kidney Foundation, The Hawaii Liver Center, and Baystate Medical Center.

Major Application Changes
In addition to 175 plus user enhancements, three significant modules were added to CDMP during the reporting period: Risk Stratification, Home Monitoring and Tele-Opthalmolgy

The new Risk Stratification engine is an independent risk calculator that can be accessed by both CDMP and other applications. Based on a comprehensive stream of anonymized patient data the engine is able to return a detailed report on the patients risk for major diabetic complications such as Retinopathy, Neuropathy, etc. The engine was designed as an independent web service that can be used by any application capable of sending and receiving XML data. Within CDMP the risk stratification data collection form was highly optimized to layer both historical and real time intervention data on a single form and is capable of returning the detailed patient reporting with nearly instant performance.

The new home monitoring application integrates the MetriLink device which allows patient's to upload from a wide variety of home monitoring devices over a standard phone line. This solution not only greatly expanded CDMP's device coverage, but also allows patients with limited internet access to easily report monitoring data from home. Within CDMP providers are able to fully register and manage patient's on the home monitoring network as well as retrieve and review results.

During this period a new generation of the tele-opthalmology application was brought into production at both the Joslin Diabetes Center and the Walter Reed Healthcare System. The new application, which was nearly a year in development, greatly expands the performance, flexibility and maintainability of the network and provides a significantly improved user interface for image evaluation and reporting.

Tele-ophthalmology application (JVN Eye Care)

Significant progress was made to bring the existing tele-ophthalmology application onto the CDMP common platform that required a close collaborative effort between the Joslin technical team involved in expanding JVN eye care functionality and the CDMP Estenda team. This infrastructure consolidation had several benefits including: Improved usability and maintainability, reduced infrastructure cost, and ability to be integrated into major DoD facilities such as Walter Reed Army Medical Center and AHLTA.

The system's capabilities for remote retina analysis, diagnosis and treatment planning were significantly improved by the development of a comprehensive reading center workstation. These new workstations consist of four high resolution monitors that allow the image reader to simultaneously view patient data, record findings, select various images, manipulate images and simulate three-dimensional retinal images. By integrating the reading station on the CDMP platform, clinicians are now able to incorporate the patient's full medical history including systemic risk factors for the progression of Diabetic Retinopathy (such as hypertension and hyperlipidema) Clinical workflow and Quality Assurance is also greatly improved with the new application that uses CDMP's patient identification and clinical worklist components. The application supports the following clinical workflow. The imaging modality is notified of scheduled patients, this notification prepopulates the modality with all required demographic and medical history data. The imaging technician uses this information during the encounter to provide real time education and identify emergent conditions. After imaging the modality transmits the completed study directly to the CDMP server via the newly developed DICOM interface. By incorporating DICOM communications in the CDMP infrastructure the program saves over $30,000 in annual licensing fees and eliminates products from a software vendor with a poor support organization. The CDMP DICOM engine stores the study and presents it for evaluation on the reader's desktop. Once presented and selected from the reader's worklist all study related information is streamed to the reading workstation. The study is presented to the reader across four screens, the reader evaluates the image using a series of image review and manipulation tools (magnification, stereo, measurement, color manipulation, etc) the reader fully documents their findings in the system (including new image quality feedback). Once the findings are saved, the CDMP determines various ophthalmologic diagnoses using a set of algorithms (these algorithms were also enhanced during this reporting period to take full advantage of the

new capabilities) The diagnoses are then presented to the reader for review, final comment and development of a patient specific treatment plan. After the user signs the study report it may be automatically emailed (via 128 bit encrypted .pdf file), faxed or electronically submitted back to the referring physician.

By moving the tele-opthalmolgy application to the CDMP platform the team was also able to incorporate a full Quality Assurance program into the software. During this reporting period the team developed both criteria and workflow for program quality assurance. They system is capable of both enforcing random, blinded peer-to-peer and peer to supervisor quality assurance reviews, reading center to imaging station reviews as well as custom group comparisons. To further improve program quality and reader productivity any reader may automatically request a supervisor or peer consult on a given study at any time during the reading process.

Key Research Accomplishments

- Development of study design and protocols for the proposed multicenter clinical studies
- Refinement of the automated retinal image analysis algorithm to improve sensitivity and specificity for detecting microaneurisms
- Retinal imaging prototype is now acquiring good quality retinal images
- Study management module for CDMP completed and ready to be used for start of clinical trials
- CDMP patient portal completed and deployed with CDMP
- Validation of retinal imaging application for detection of non-diabetic retinal findings
- Algorithm development for detecting elevated retinal features has been completed and will undergo clinical testing with comparisons to OCT measurements of retinal thickness
- All proposed Prospective Research Studies are either in recruitment, in process of data analysis, or completed
- Associated manuscripts for completed studies are in preparation for submission to peer review journals
- Completed integration of JVN Eye Care into CDMP with development of next generation software
- JVN application is completed and being integrated into AHLTA
- Definition of requirements for a retinal digital imaging camera, development of camera and initiation of clinical validation trial to determine diagnostic accuracy
- Expanded CDMP functionality to include a broader range of home monitoring devices in partnership with iMetrikus. Interface with iMetrikus completed. Demostration project ready to commence
- Implementation of data monitoring in CDMP to provide quality assurance reporting on the JVN eye care program. Quality assurance program now being used as a model for Indian Health Service and VA
- Establishment of a research data warehouse of JVN eye care patients with a manuscript in preparation, using this data, comparing Joslin patients undergoing JVN eye care intervention compared to Joslin patients receiving standard care with respect to outcomes such as compliance to eye care referrals, glycemic control, lipid levels, blood pressure, and foot examinations. Paper has been accepted for publication

Reportable Outcomes

Patents Issued

United States Patent # 7,338,167 on Retinal Imaging System issued March 4, 2008

Invited Presentations

2003 *Ellerbrock Continuing Education Program, American Academy of Optometry Annual Meeting, Dallas, TX.* "Ocular Telemedicine: Challenges and Opportunities"

2003 *Maine Optometric Association Fall Conference, Dixville Notch, NH.* "The Role of Telemedicine in Preserving Vision: Challenges and Clinical Adaptation"

2003 OptoEast 2003, Atlantic City, NJ. "The Role of Telemedicine in Preserving Vision" Challenges and Clinical Adaptation"

2003 Temedicine and Advanced Technology Research Center (TATRC) Ocular Telehealth Scientific Workshop, July 8-10.
* Teleophthalmology Outcomes in Diabetic Retinopathy

2003 American Telemedicine Association Annual Meeting, Orlando, FL.
* Chair—Ocular Telehealth Special Interest Group Program: Ocular Telehealth: Focus on Diabetic Retinopathy and Other Applications
* Joslin Vision Network Case Reports

2004 *American Telemedicine Association Annual Meeting, Tampa, Florida*
*Ocular Telehealth Special Interest Group Short Course Program: Coordinator and Chairperson.
* Joslin Vision Network Ocular Telehealth Programs in a Clinical Setting

2004 *NEWENCO Center for Graduate Education. Certificate Program—February 2004*
*Diabetes and Tele-Optometry

2005 American Telemedicine Association Annual Meeting: Denver, CO
*Telehealth Practice Recommendations for Diabetic Retinopathy
*Joslin Vision Network: Category 3 Telemedicine for Diabetic Retinopathy

2005 Longwood Medical Ophthalmology Monthly Conference. June 2005.
*Joslin Vision Network Diabetes Eye Care Model: Principles and Applications

2005 Canadian Ophthalmological Society Annual Meeting. Edmonton, Alberta, Canada *American Telemedicine Association Telehealth Practice Recommendations for Diabetic Retinopathy

2005 American Telemedicine Association Annual Meeting: Denver, CO
Telehealth Practice Recommendations for Diabetic Retinopathy Joslin Vision Network: Category 3 Telemedicine for Diabetic Retinopathy

2005 Longwood Medical Ophthalmology Monthly Conference. June 2005.
Joslin Vision Network Diabetes Eye Care Model: Principles and Applications

2005 Canadian Ophthalmological Society Annual Meeting. Edmonton, Alberta, Canada *American Telemedicine Association Telehealth Practice Recommendations for Diabetic Retinopathy*

2005 International Symposium on Diabetic Retinopathy, Medical Council of India, Aravind Eye Hospital, Madurai, India. 3-4 September 2005
Telemedicine Practice Recommendations for Diabetic Retinopathy
Joslin Vision Network Telemedicine Diabetes Eye Care Model: Principles and Applications

2005 Harvard Medical School: Diabetes Mellitus State of the Art: An Integrative Approach to Understanding and Managing Diabetes *The Joslin Vision Network—Validated Telemedicine for Diabetic Retinopathy*

2005 Joslin Diabetes Center; Affiliated Center Annual Meeting
Joslin Vision Network Telemedicine Diabetes Eye Care Model: Principles and Applications

2005 Koch Eye Associates Grand Rounds, Warwick, RI.
Perspectives: Diabetic Retinopathy and Telemedicie

2006 Optometric Retina Society. Retinal manifestations of Vascular and Related Systemic Disease—3rd Annual Meeting, Boston, MA
Diagnosing and Managing Diabetic Retinopathy: Essentials for the Primary Care Optometrist

2006 Annual Meeting, San Diego, CA.
Imager and Grader Certification and Quality Assurance in Ocular Telemedicine

2006 Annual Meeting, San Diego, CA.
Imager and Grader Certification and Quality Assurance in Ocular Telemedicine

2006 Harvard Medical School: Diabetes Mellitus State of the Art: An Integrative Approach to Understanding and Managing Diabetes. *The Joslin Vision Network—Validated Telemedicine for Diabetic Retinopathy*

2007 International Symposium on Diabetic Retinopathy and Age-Related Macular Edema (*via* Teleconference), Medical Council of India, Aravind Eye Hospital, Madurai, India. 5-7 January 2007. *Telemedicine for*

Diabetic Retinopathy

2007 Center for Innovation in Diabetes Education (CIDE) Joslin Diabetes Center *Validated Telemedicine for Diabetic Retinopathy: The Joslin Vision Network Diabetes Eye Care Program*. 30 March 2007.

2007 Joslin Diabetes Center—Clinical Diabetes and Metabolism Monday Conference Series. T*elemedicine for Diabetic Retinopathy: The Joslin Vision Network Diabetes Eye Care Program.* 9 April 2007.

2007 Allied Physicians Group Annual Meeting, Boston, MA*. Diabetic Retinopathy Assessment in the Primary Care Environment: The Joslin Vision Network Diabetes Eye Care Program*

2007 Optometric Retina Society Annual Meeting, Las Vegas, NV. *Diabetic Retinopathy – Novel Prevention Approaches and Treatment.* 14-16 April 2007.

2007 American Telemedicine Association 2007 Annual Meeting, Nashville, TN. *Impact of Field Selection on Nonmydriatic Retinal Imaging for Diabetic Retinopathy in the Joslin Vision Network.*

2007 American Academy of Optometry Annual Meeting, Tampa, FL
Ocular Telemedicine: Expanding the Boundaries of Diabetes Eye Care

Proceedings of Meetings/Abstract and Poster Presentations

1. Coll KJ, Birkmire-Peters D, Katalinic P, Tolson A, Cavallerano A, **Cavallerano J**, Bursell S, Dunlap W, Aiello LM. Joslin Vision Network Impact on Clinical Operations at Tripler Army Medical Center. 2003 American Telemedicine Association Annual Meeting, Orlando, FL.
2. Cavallerano AA, Katalinic P, Cavallerano J, Hock K, Tolson A, DeVita J, Aiello LM, Blake B, Rynne M, Joslin Vision Network Clinical Team. Joslin Vision Network Examination for Diabetic Retinopathy in a Veterans Hospital - Report #3. 2003 American Telemedicine Association Annual Meeting, Orlando, FL.
3. Cavallerano J, Aiello LM, Cavallerano AA, Katalinic P, Bursell SE, Aiello LP, Joslin Vision Network Clinical Team. Joslin Vision Network Imaging without Pupil Dilation for Annual Diabetes Retinal Examination. 2003 American Telemedicine Association Annual Meeting, Orlando, FL.
4. Chow SP, Cavallerano J, Katalinic P, Hock K, Tolson A, Kirby A, Aiello LM, Aiello LP, Bursell S. Comparison of nonmydriatic digital retinal imaging with dilated clinical eye exam for detecting non-diabetes-related pathology in diabetic patients. Poster. 2004 ARVO Annual Meeting. Invest. Ophthalmol. Vis. Sci. 2004 45: E-Abstract 4120.
5. Cavallerano J. American Telemedicine Association Position Statement: Clinical Practice Recommendations for Telehealth for Diabetic Retinopathy. 2004 American Telemedicine Association Annual Meeting: Tampa, FL
6. Coll K-J, Birkmire-Peters D, Pelletier M, Cavallerano J, Bursell S, Dunlap W, Winkle RK, Aiello LM. Joslin Vision Network: Evidence supporting need for comprehensive disease management. 2004 American Telemedicine Association Annual Meeting: Tampa, FL.
7. Chow SP, Cavallerano J, Katalinic P, Hock K, Tolson A, Kirby A, Aiello LM, Aiello LP, Bursell S. Detection of non-diabetes-related pathology in diabetic patients using nonmydriatic digital retinal imaging compared to dilated clinical eye exam. 2005 American Telemedicine Association Annual Meeting: Denver, CO.
8. Hock K, Cavallerano J, Kirby R, Frey L, Tolson A, Aiello LM. Poster. The effect of an adult-diabetes-clinic-based nonmydriatic retinal imaging program on access to diabetes eye care. American Diabetes Association 2005 Annual Meeting. San Diego, CA
9. Chow SP, Cavallerano **J**, Katalinic P, Hock K, Tolson A, Kirby A, Aiello LM, Aiello LP, Bursell S. Detection of non-diabetes-related pathology in diabetic patients using nonmydriatic digital retinal imaging compared to dilated clinical eye exam. 2005 American Telemedicine Association Annual Meeting: Denver, CO.
10. Hock K, Cavallerano J, Kirby R, Frey L, Tolson A, Aiello LM. Poster. The effect of an adult-diabetes-clinic-based nonmydriatic retinal imaging program on access to diabetes eye care. American Diabetes Association 2005 Annual Meeting. San Diego, CA
11. Sackey J, Heffernan J, Tolson A, Cavallerano J. Innovations in Managing Diabetic Retinopathy in a Primary Care Practice. Society of General Internal Medicine (SGIM) 29th Annual Meeting. Los Angeles, CA.
12. Ceron OM, Simmons EP, Robles L, Garcia E, Cavallerano J, Timothy N, Calderon R, Caballero AE, Aiello LP. Integration of Ocular Telemedicine and Specialty Diabetes Care in a Latino Population. ARVO 2006 Annual Meeting, Fort Lauderdale, FL.

13. Doughty J, Heffernan J, Sackey J, Chew R, Eagan S, Tolls D, Aiello LP, Tolson A, Cavallerano J. Nonmydriatic Retinal Imaging for Diabetic Patients in a Primary-Care Setting. American Telemedicine Association 2006 Annual Meeting, San Diego, CA.
14. Hock K, Cavallerano J, Kirby R, Frey L, Tolson A, Bursell S-E, Aiello LM. Nonmydriatic Retinal Imaging in an Adult Diabetes Clinic. American Telemedicine Association 2006 Annual Meeting, San Diego, CA.
15. Birkmire-Peters, D.P. (2006). Use of Human Factors Principles in Telemedicine Research. Paper presented in The People Make the Difference: Human Factors in Telemedicine Panel at the 11th Annual Meeting of the American Telemedicine Association, San Diego, CA.
16. Coll, K.J., Birkmire-Peters, D.P., Pelletier, M.V., Cavallerano, J., Bursell, S., Winkle, R.K. & Aiello, L.M. (2005, April). Joslin Vision Network: Eye Care Visits Following JVN Imaging. Poster presented at the 10th Annual Meeting of the American Telemedicine Association, Denver, CO.
17. Bursell SE, Birkmire-Peters D, Conlin P, Fonda S, Kedziora RJ, Paulsen C, Perkins J, Rodbard D, Vigersky R. Human Factors Analysis: Joslin Vision Network Comprehensive Diabetes Management. American Telemedicine Association 2006 Annual Meeting, San Diego, CA.
18. Hock K, Cavallerano J, Kirby R, Frey L, Tolson A, Aiello LM. Poster. The effect of an adult-diabetes-clinic-based nonmydriatic retinal imaging program on access to diabetes eye care. American Diabetes Association 2005 Annual Meeting. San Diego, CA
19. Sackey J, Heffernan J, Tolson A, Cavallerano J. Innovations in Managing Diabetic Retinopathy in a Primary Care Practice. Society of General Internal Medicine (SGIM) 29th Annual Meeting. Los Angeles, CA.
20. Ceron OM, Simmons EP, Robles L, Garcia E, Cavallerano J, Timothy N, Calderon R, Caballero AE, Aiello LP. Integration of Ocular Telemedicine and Specialty Diabetes Care in a Latino Population. ARVO 2006 Annual Meeting, Fort Lauderdale, FL.
21. Doughty J, Heffernan J, Sackey J, Chew R, Eagan S, Tolls D, Aiello LP, Tolson A, Cavallerano J. Nonmydriatic Retinal Imaging for Diabetic Patients in a Primary-Care Setting. American Telemedicine Association 2006 Annual Meeting, San Diego, CA.
22. Hock K, Cavallerano J, Kirby R, Frey L, Tolson A, Bursell S-E, Aiello LM. Nonmydriatic Retinal Imaging in an Adult Diabetes Clinic. American Telemedicine Association 2006 Annual Meeting, San Diego, CA.
23. Prakash M, Cavallerano JD, Murtha TJ, Sun JK, Clermont AC, Hamam RN, Bursell S-E, Aiello LP. *Comparison of Automated Digital Retinal Images, ETDRS 35mm 7-Standard Field Color Stereoscopic Retinal Photography and Retinal Examination for Assessment of Diabetic Retinopathy Severity.* ARVO 2007 Annual Meeting, Ft. Lauderdale, FL
24. Aiello LM, DeVitt P, Lopez G, Seligson M, Hock K, Timothy N, Eagan S, Cavallerano J, Joslin Vision Network Reader Team. *Integration of Ocular Telemedicine in a Community Health Center.* American Telemedicine Association 2007 Annual Meeting, Nashville, TN.
25. Timothy N, Aiello LM, Koch PS, Geltzer A, Kachadoorian H, McHale M, Hock K, Eagan S, Cavallerano J, Joslin Vision Network Reader Team. *Integration of a Telemedicine Program for Diabetic Retinopathy in an Urban Ophthalmology Practice.* American Telemedicine Association 2007 Annual Meeting, Nashville, TN.
26. Cavallerano J, Francis T, Hock K, Tolson A, Aiello LM, Eagan S. *Impact of Field Selection in Nonmydriatic Retinal Imaging for Diabetic Retinopathy in the Joslin Vision Network.* American Academy of Optometry 2007 Annual Meeting, Tampa, FL.
27. Jeonifer Garren, MPH, Stephanie J. Fonda, Ph.D, Sven-Erik Bursell, Ph.D., Paul R. Conlin, M.D., Robert A. Vigersky, M.D., Deborah Birkmire-Peters, Ph.D. Test-Retest Reliability of a New Screening Questionnaire for People with Diabetes. CDC Diabetes Translational Conference May 2007

Publications

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Conclusions

The study design for the proposed multicenter prospective clinical trials have been completed, have received approval though participating organization human subjects review boards, and have been approved through HSRRB. The proposed studies are in various stages of initiation, recruitment, or completion. For completed studies data has been analyzed and manuscripts are being prepared for submission. These prospective studies are important as they are designed to demonstrate both clinical efficacy and cost effectiveness of the JVN program. If the hypothesis of clinical efficacy and cost effectiveness are born out by the results from these trials then the broad introduction of this application into the health care system will be facilitated and could result in significant health care dollar savings associated with the care of patients with diabetes.

The Comprehensive Diabetes Management Program (CDMP) application has undergone a number of versions and we have developed significant new functionality to the application. The CDMP architecture was key in the seamless integration of the JVN eye care program as a module of the CDMP application. The integration of JVN eye care into CDMP was a critical step to complete integration of a single application into AHLTA.

The JVN Eye care module has also undergone significant revision that incorporates increased reporting functionality for both diabetic retinopathy and other non-diabetes related eye diseases such as age related macula degeneration. The reporting functionality also leverages CDMP risk assessment so that a clinical plan for appropriate eye care also takes into account systemic risk factors that may increase the progression of diabetic retinopathy. Additionally, because analog video cameras, are no longer available we have had to research digital video cameras that can be used to meet the requirements for low light level retinal imaging without pupil dilation. This research has been completed in partnership with MegaVision where we have developed a digital camera with superior imaging capabilities that continues to meet JVN requirements for low light level imaging. This camera is currently undergoing rigorous clinical validation for diagnostic accuracy.

With the completion of the CDMP patient portal (Diabetes Management Everywhere (DME) and its utilization in a prospective clinical trial we have worked on expanding DME functionality to support a broader range of home monitoring devices. In order to accomplish this we have established a partnership with iMetrikus who have developed a universal adaptor that allows communication between multiple devices through DME to the CDMP server. The DME portal facilitates secure communication between patient and provider with respect to downloaded patient information such as weight, blood pressure, and blood glucose monitoring values. The system also allows patients to down load digital images for review by care managers, for example patients can down load images of their meals for discussion regarding portion size and calories with nutritionists.

Furthermore, the clinical studies currently proposed and underway in this contract will be completed as part of the new contract with University of Hawaii. As part of this effort we will continue with Estenda to provide continued support and maintenance of the CDMP application for all sites. Additionally Estenda will work with investigators to implement new functionality as the reduced funding permits. The completion of the JVN eye care component of the proposed work will now be performed under a subcontract from the University of Hawaii to the Joslin Diabetes Center.

APPENDICES:

Appendix 1: Presented ARVO 2005

IMPROVED AUTOMATED DIGITAL RETINAL IMAGE ANALYSIS FOR DETECTION OF DIABETIC RETINOPATHY THROUGH IMAGE QUALITY RESTORATION

P. Soliz[1], B Raman[2], SC Nemeth[3], S Barriaga[1], G. Zamora[3], and S.E. Bursell[4], [1]ORION International Technologies, Albuquerque, NM, [2]University of New Mexico, Albuquerque, NM, [3] Kestrel Corporation, Albuquerque, NM, [4] Joslin Diabetes Center, Boston MA

OBJECTIVE

Although retinal imaging technology is advancing at a very high rate, it remains impractical and economically infeasible to deploy only the highest available resolution (number of pixels) digital cameras. The purpose of this study was to assess the effectiveness of image "enhancement" techniques on image quality and the subsequent impact on lesion detection and visualization for patients with diabetic retinopathy (DR).

Background

The transition of technology into eye clinics and applications such as telemedicine are constrained by economics, data storage and communications requirements.

Intuitively, better image quality through finer pixel representation of a medical image should improve the sensitivity and specificity with which a physician, human grader or a computer-based algorithm can detect lesions associated with DR.

Decisions to upgrade clinical fundus imagers to "high-end" imaging tech nologies may unnecessarily add to the healthcare costs, will require additional electronic storage capacity, or additional bandwidth in telemedi cine applications. These requirements must be assessed in terms of their value added.

In making these decisions, clinical significance is often not thoroughly evaluated or ignored. This is partially due to the lack of a means for quan titatively evaluating new imaging technologies.

Below is a 2000 by 2000 image pre-processed with two different techniques:

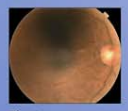

Fig. 1.
Original image
Entropy = 6.3, Contrast =36.7

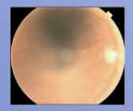

Fig. 2.
Histogram equalized
Entropy = 6.9, Contrast =114.6

Fig. 3.
Spatially-based constrast enhancement
Entropy = 6.3, Contrast =131.5

Motivation

New or improved imaging technology is needed to increase the sensitivity for detecting disease in retinal images.

One of the most common diagnostics used in the clinic for monitoring treatment or progression of retinal diseases is the fundus image.

Technology to improve image quality at little or no added cost is required for a number of applications in the healthcare system, including remote screening and clinical setting sreening and clinical setting.

Higher resolution and greater contrast for improved earlier detection and greater sensitivity.

METHODS

- Joslin Vision Network: 480 by 640, non-mydriatic, stereo images, three fields
  - The low resolution images were 640 by 480 pixels with 45 degree field of view and collected non-mydriatically. Ninety-seven subjects, 74 with no DR and 23 with DR were included.
- The University of Texas Health Science Center, San Antonio, TX: 1000 by 1000
- Apply image illumination correction and contrast enhancement
- Calculate image quality (IQ) metrics to characterize each image
  - Entropy
  - Contrast
  - Spatial Frequency
  - etc.
- Evaluate the effects of image processing for contrast enhancement
- Assess image quality effects on automatic lesion detection (microaneurysm segmentation) using Joslin Vision Network images: 480 by 640, non-mydriatic, stereo images with 45 degree field of view and collected non-mydriatically. 97 subjects (74 with no DR and 23 with not DR) were included.

Image Quality Metrics were calculated for image types/modalities:

$$Contrast = \sum_{i=1}^{N_g-1} n^2 \left\{ \sum_{i=1}^{N_g} \sum_{\substack{j=1 \\ |i-j|=n}}^{N_g} p(i,j) \right\} \qquad H = -\sum P(i)\log(P(i))$$

- Sample Images with IQ metrics:

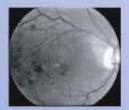

Figure 4. (1543-01)
Green channel original.
Entropy = 6.9, Contrast =10.0
Courtesy of UTSA

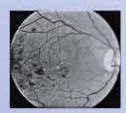

Figure 5. (1543-01)
Contrast enhanced.
Entropy = 6.7, Contrast =12.1

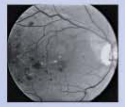

Figure 6. (1543-01)
contrast enhanced and edge sharpened.
Entropy = 7.3, Contrast =91.4

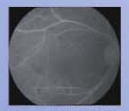

Figure 7. (1543-11)
Original FA image.
Entropy = 5.8, Contrast =8.5

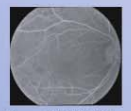

Figure 8. (1543-11)
contrast enhanced.
Entropy = 5.7, Contrast =44.8

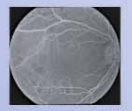

Figure 9. (1543-11)
contrast enhanced and edge sharpened.
Entropy = 6.5, Contrast =46.4

METHODS (cont'd.)

Computer-based MA Segmentation:

The computer-based digital retinal photo screening system screens low quality images based on image quality metrics prior to the automatic segmentation of MAs.

Uneven lighting is common to most retinal images, especially when illuminated non-mydriatically. An image flattening process is applied to remove the uneven illumination.

The MAs were segmented using a top-hat transformation [2].

Two data sets were used in the study:

The higher resolution images were 1400 by 1200 pixels with 30 degree field of view and collected through pharmacalocially dilated pupils. 10 patients with DR and 8 without DR were included.

Joslin Vision Network Images

RESULTS

High resolution fundus images

- A clinical sensitivity of 90% and a specificity of 87.5% were achieved. The dataset is very small and no validation was performed on an independent dataset.

Low resolution fundus images

- A clinical sensitivity of 69% and a specificity of 68% were achieved for the training data.
- A clinical sensitivity of 83% and a specificity of 69% were achieved for the test data.
- Image pre-processing improved sensitivity and specificity to 92% and 74% respectively
- The positive predictive value was found to be greater than the prevalence of both the training and testing sets

Qualitatively and quantatively, the processed images demonstrated removal of illumination artifacts and help the analyst to better visualize lesions, especially in underexposed regions of the image.

CONCLUSION

This project demonstrated that image quality through image enhancement techniques can add significantly to the detection of lesions through automated means or in the visualization by readers.

Acknowledgments: Funding for this study were provided in part from a contract sponsored by the Department of the Army through Cooperative Agreement DAMD 17-3-02-0062 for the Joslin Department of Defense (DOD)/Department of Veterans Affairs Program. The content of the information within this program does not necessarily reflect the position or the policy of the government, and no official endorsement should beinferred. Data were also provided by Dr. Tom Fitzsimmons from the University of Texas Health Science Center, San Antonio TX. The MA segmentation research was performed by PS and BR while employed by Kestrel Corporation, Albuquerque, NM. Our thanks to Mr. Gene Butler (President/CEO of Kestrel) for allowing us to present those results.

Appendix 2: Presented ATA 2005

THE EFFECT OF IMAGE QUALITY ON MANUAL AND COMPUTER-BASED SCREENING FOR DIABETIC RETINOPATHY

P. Soliz[1], S. E . Bursell[2], S. Russell[3], W. Bauman[4], and B. Raman[5]; [1]Vision Quest Biomedical, Albuquerque, NM, [2]Joslin Diabetes Center, [3]University of Iowa Department of Ophthalmology, [4]Brooke Army Medical Center, San Antonio, TX, [5]University of New Mexico, Electrical and Computer Engineering Dept., Albuquerque, NM

OBJECTIVE

To assess the impact of image quality on the effectiveness of detecting diabetic retinopathy (DR) lesions in retinal images.

Background

Today's telemedicine systems are constrained by economics and communications capabilities.

Intuitively, better image quality through finer pixel representation of a medical image should improve the sensitivity and specificity with which a human greater or a computer-based algorithm can detect lesions associated with DR.

Decisions to upgrade to "high-end" imaging technologies that may unnec unnecessarily add to the cost of the medical service and will require additional bandwidth must be assessed in terms of their value added.

Clinical significance is often not thoroughly evaluated or ignored.

Fig. 1.
480 x 640 pixels

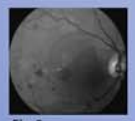

Fig. 2.
1k x 1k pixels

Fig. 3.
2k x 2k pixels

Motivation

New or improved imaging technology is needed to increase the sensitivity for detecting disease in retinal images.

One of the most common diagnostics used in the clinic for monitoring treatment or progression of retinal diseases is the fundus image.

Technology to improve image quality at little or no added cost is required for a number applications in the healthcare system, including remote screening and clinical setting sreening and clinical setting.

Higher resolution and contrast for improved earlier detection and greater sensitivity.

METHODS

Data from three different fundus cameras were provided by:

- Joslin Vision Network: 480 by 640, non-mydriatic, stereo images, three fields
  - The low resolution images were 640 by 480 pixels with 45 degree field of view and collected non-mydriatically. Ninety-seven subjects, 74 with no DR and 23 with DR were included.
- The University of Texas Health Science Center, San Antonio, TX: 1000 by 1000
- The University of Texas Medical Branch, Galveston, TX: 2000 by 2000,
- Apply image quality (IQ) metrics to characterize each image
  - Entropy – Spatial Frequency
  - Contrast – etc.
- Develop a preliminary, qualitative model that correlates visual perception of IQ with these metrics
- Evaluate the effects of image processing for contrast enhancement
- Apply automatic lesion detection (microaneurysm segmentation)

Image Quality Metrics were calculated for image types/modalities:

$$Contrast = \sum_{i=1}^{N_g-1} n^2 \left\{ \sum_{i=1}^{N_g} \sum_{\substack{j=1 \\ |i-j|=n}}^{N_g} p(i,j) \right\} \qquad H = -\sum P(i)\log(P(i))$$

- **Sample Images with IQ metrics:**

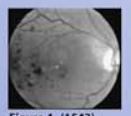

Figure 4. (1543)
Green channel.
Entropy = 6.7, Contrast =12.1
Spatial Frequency = 4.1
Courtesy of UTSA

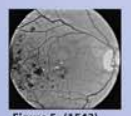

Figure 5. (1543)
Green channel.
Contrast enhanced
Entropy = 7.2, Contrast =132.7
Spatial Frequency = 14.0

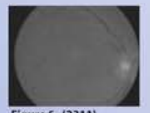

Figure 6. (2311)
Green channel.
Entropy = 5.3, Contrast =11.6
Spatial Frequency = 4.6
Courtesy of UTSA

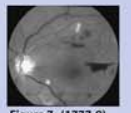

Figure 7. (1777-9)
Green channel.
Entropy = 5.2, Contrast =10.4
Spatial Frequency = 4.1
Courtesy of UTSA

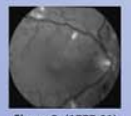

Figure 8. (1777-01)
Green channel.
Entropy = 6.1, Contrast =8.3
Spatial Frequency = 3.7
Courtesy of UTSA

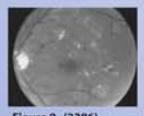

Figure 9. (2286)
Green channel.
Entropy = 6.3, Contrast =33.8
Spatial Frequency = 7.4
Courtesy of UTSA

METHODS (cont'd.)

Computer-based MA Segmentation:

The computer-based digital retinal photo screening system first identifies automatically those digital fundus images of sufficient quality for the automatic segmentation of MAs based on image quality metrics.

Uneven lighting is common to most retinal images, especially when illuminated non-mydriatically. An image flattening process is applied to remove the uneven illumination.

The MAs were segmented using a top-hat transformation [2].

Two data sets were used in the study:

The higher resolution images were 1400 by 1200 pixels with 30 degree field of view and collected through pharmacalocially dilated pupils. 10 patients with DR and 8 without DR were included.

JVN Data

RESULTS

High resolution fundus images

- A clinical sensitivity of 90% and a specificity of 87.5% were achieved. The dataset is very small and no validation was performed on an independent dataset.

Low resolution fundus images

- A clinical sensitivity of 83% and a specificity of 69% were achieved for the training data.
- A clinical sensitivity of 83% and a specificity of 69% were achieved for the test data.
- Image preprocessors improved sensitivity and specificity to 92% and 74% respectively
- The positive predictive value was found to be greater than the prevalence for both the trainint and testing sets

CONCLUSION

This project demonstrated that image quality through image enhancement techniques can add significantly to the sensitivity and specificity of screening for DR in at risk patients without increase bandwidth requirements, and with little added cost.

Acknowledgments: Funding for this study were provided in part from a contract sponsored by the Department of the Armythrough Cooperative Agreement DAMD 17-3-02-0062 for the Joslin Department of Defense (DOD)/Department of Veterans Affairs Program. The content of the information within this program does notnecessarily reflect the position or the policy of the government, and no official endorsement should beinferred. Data were also provided by Dr. Tom Fitzsimmons and Dr. Helen Li from the University of TexasHealth Science Center, San Antonio TX and the University of Texas Medical Branch, Galveston, TX. The researchwas performed by PS and BR while employed at Kestrel Corporation, Albuquerque, NM. Our thanks to Mr. Gene Butler (President/CEO of Kestrel) for supporting the research represented in this material.

Appendix 3: Copy of first page of published article in Retinal Physician

Validated Telemedicine for Diabetic Retinopathy

The Joslin Vision Network Diabetes Eye Care Program

JERRY CAVALLERANO, OD, PhD • SVEN-ERIK BURSELL, PhD • LLOYD M. AIELLO, MD

Approximately 40% of Americans with diabetes mellitus (DM) do not receive eye examinations for diabetic retinopathy (DR), as suggested by the American Diabetes Association Clinical Practice Recommendations;[1] consequently, only 60% of Americans with DM receive the sight-saving care that has been proved effective over the last 40 years.[2-6] Obstacles that limit or prevent access to appropriate diabetes eye care include geographic and economic barriers, patient or provider unawareness of the value of regular diabetes eye care, patient fear or reluctance to undergo dilated fundus exam, and the fact that DR, even in advanced states, frequently is asymptomatic. Ocular telemedicine for DR, appropriately deployed and properly validated, has the potential to deliver high-quality chronic, urgent, and emergent care, limited only by the ability to deploy the latest technologies.

WHAT IS TELEMEDICINE?

The American Telemedicine Association (ATA) defines telemedicine as "the use of medical information exchanged from one site to another via electronic communications to improve patients' health status."[7] Telemedicine is the practice of medicine that is interventional and includes relationships between patient and physicians or their surrogates. Telehealth is closely associated with telemedicine and encompasses a broader definition of remote health care that relies on videoconferencing, electronic patient portals to record and monitor vital signs, transmission of digital images and records, electronic consultation, patient education, and continuing medical education.

For many reasons, DR presents an ideal model for disease management by telemedicine and telehealth. There are an estimated 21 million Americans with DM and more than 150 million people worldwide with the condition, with the number of cases increasing at epidemic rates.[8,9] DM is a complex, chronic disease that requires lifelong care. Everyone with DM is at risk of developing DR, which is a well characterized, sight-threatening microvascular complication of DM;[10,11] there are solid, evidence-based clinical management strategies established over the last 35 years that are effective in preserving vision; DR is frequently asymptomatic in its most treatable stages; the prevalence and incidence of DM, with its accompanying complications, are growing at alarming rates worldwide; and many persons with DM do not receive regular eye care and sight-preserving treatments, even when such care and treatments may be readily available. DM poses significant personal and societal problems, remaining a leading cause of vision loss in industrialized countries. Multiple nationwide clinical trials, including the Diabetic Retinopathy Study,[12] the Early Treatment Diabetic Retinopathy Study (ETDRS),[13,14] the Diabetes Control and Complications Trial,[15] and the United Kingdom Prospective Diabetes Study,[16] have demonstrated effective care and treatment programs for DR, but because many individuals who would benefit from sight-preserving care do not receive this care, DM is a significant cause of preventable vision loss and blindness worldwide.[17]

While telemedicine has the potential to extend sight-preserving diabetes eye care, it is crucial that telemedicine programs match the quality of care expected in traditional clinical settings. Because there are evidenced-based methods to preserve vision for those with DM faced with an increased risk of vision loss, ocular telemedicine should include and apply these proven methods. The ATA, recognizing the importance of evidence-based care in telemedicine, established consensus recommendations for ocular

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Appendix 2: CDC Diabetes Translational Conference May 2007

Test-Retest Reliability of a New Screening Questionnaire for People with Diabetes

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INTRODUCTION:

Daily self-care behaviors carried out by the person with diabetes are of central importance in attaining good blood glucose control. This is achieved through patient adherence to:

- A healthy diet
- Regular exercise
- Appropriate use of diabetes medications (insulin and oral agents)
- Regular self-monitoring of blood glucose (SMBG) to guide daily management decisions
- Hypoglycemia management and prevention
- Foot care, clinic visits, diabetes education, and various necessary medical screenings

Many environmental and patient factors can influence implementation of the diabetes treatment plan by the patient. Typically little time is spent in busy, primary care settings (not specializing in diabetes) assessing each patient's factors and current behaviors that can influence their diabetes treatment/self-management plan. The opportunity to implement a tailored care management approach with diabetes patients is lost.

Thus, a consortium of diabetes experts from the Joslin Diabetes Center, Veterans Affairs, the Department of Defense, and the Indian Health Service developed a screening instrument to be used in busy clinical settings to quickly assess patient's factors and behaviors. The BAT draws key questions from other validated assessments and is intended to generate further evaluation and/or referrals.

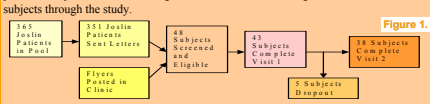
Since this instrument is new, we are conducting studies to evaluate its test-retest reliability, criterion validity, and predictive validity. This study reports on the test-retest reliability of the BAT.

MATERIALS AND METHODS:

Study Design:

This is an observational study with two measurements per study subject taking place 2 to 4 weeks apart. The study subjects were recruited using flyers and mass mailings to to potential subjects identified through medical record review. Figure 1 shows the flow of subjects through the study.

Figure 1.



Site and Subjects:

Recruitment for study subjects occurred at Joslin Diabetes Center (Boston), a tertiary care specialty hospital. Subjects were considered eligible if they had diabetes for 2 years or more, were 18 years old or older, and comfortable speaking and reading English.

Measures:

At both visits the subject completed a blood glucose test, a test of cognitive functioning, and the BAT questionnaire. Social-demographic data were collected during the first visit as well. Basic health data was gathered from the subjects' medical records at the end of the study.

Table 1 shows the BAT questionnaire questions along with their variable names. Certain questions are "flagged" to indicate that they were intended to result in clinician follow-up or referral. These are the questions we examined the test-retest reliability of.

Table 1. Behavioral Assessment Tool

Question	Variable name	
Is English your native language?	english	
When you learn something new, does it help to hear it in your native language?	learnlang	
Would you like someone who speaks your native language to help you complete this survey?	speaklang	
Do you have problems reading and understanding written materials?	readwrite	
Would you like someone to read the survey questions to you?	readques	
When were you first told you have diabetes?	whendiagnose	
On a typical day, how many servings of fruits and vegetables do you eat?	servfruitveg	*
During the past 7 days, how often did you eat 3 meals a day (that is, you did not skip a meal)?	eat3meals	*
How many times in the past 7 days have you eaten food prepared in a restaurant or cafeteria?	restaurant	*
How would you describe your physical activity level?	physactivity	*
In the last 7 days, how many times were you moderately to very physically active for 30 minutes or more?	modtostren	*
How often do you check your blood sugar?	smbg	*
In the last 7 days, how often did you miss taking your diabetes pills or insulin?	missmeds	*
During the past month have you often been bothered by feeling down, depressed, or hopeless?	depressed	*
During the past month have you often had little interest or pleasure in doing things?	nopleasure	*
Do you drink alcohol?	alcohol	*
Are you concerned about your drinking?	concernalc	*
Do you smoke cigarettes, cigars, a pipe, or chew tobacco?	smoke	*
In general, would you say your health is:	selfratehealth	*
Have you been examined by an eye doctor in the last 12 months?	eyeexam	*
How often do you check your feet for sores, cuts, or bruises?	checkfeet	*
Have your feet been examined by a doctor in the last 12 months?	footexam	*
Do you use other healing methods or remedies in addition to those prescribed for	allmeds	
Do you have family and friends you can ask for help?	havefamfriends	*
Do your family and friends live in your house or nearby?	famfriendsnear	*
Do you agree with the following statement? My family and friends support me by encouraging me to do things to improve my health.	support	*
Do you have problems getting to the clinic?	probgetclinic	*
How long does it usually take you to get to the clinic?	timetoclinic	
How do you usually get to the clinic?	howclinic	
How do you like to learn about new things?	video, read, othershow, discussions, listening, computers, class, otherways	
How much have you learned about diabetes from reading materials, visits with nurses, or attending classes?	howmuchlearn	
Would you like to learn more about taking care of your diabetes?	learnmore	
Which **BEST** describes you? (Choose only one answer.)	employfl, employpt, disabled, retired, student, lookwork, otherwork	
Do you have any vision problems?	vision	*
Do you have any hearing problems?	hearing	*
Do you have any problems walking?	walking	*
Do you have problems remembering things?	remembering	*
Do you have any money issues that affect your ability to take care of any of the following items?	probpaymeds, probpayfood, probpaytransport, probpaysmbg	*
Did you complete these questions with help from another person?	hadhelp	

* = questions represent questions that have clinical relevance for follow-up or referral.

Statistical Analysis:

Demographic characteristics of the sample are presented as descriptive statistics. Spearman rank coefficients (ordinal) or Cramér's *V* (nominal) and agreement percentages were calculated to examine the test-retest reliability of the "flagged" BAT questions. The BAT questions' reliability were also compared against other reliable instruments for questions about nutrition, physical activity, blood glucose monitoring, alcohol use, mood, and social support. Statistical analysis was carried out using the statistical package SAS 9.1.

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RESULTS:

The majority of the sample was female, white, and had type 2 diabetes (70%, 84%, and 70% respectively). The average age of the subjects was 61 ± 13 years. Eighty-eight percent of the subjects completed the study; dropouts were not significantly different demographically from completed subjects. Table 2 list the demographics of the population for this study, i.e. age group, gender, race/ethnicity, education, diabetes type, and income.

Overall test-retest reliability ranged from -0.06 to 1.0 with seventy percent of all BAT questions having an acceptable test-retest reliability (r ? 0.50). Among the BAT questions being compared against other reliable questionnaires the overall test-retest reliability ranged from 0.27 to 0.98 with eighty percent of the BAT questions having an acceptable test-retest reliability.

Table 3 list all of the percent agreements and Spearman rank coefficient or Cramér's *V* with p-values for the BAT questionnaire questions.

Table 2. Demographics

Parameters	#	%
Age Group		
= 49 years	9	20.93%
50-59 years	14	32.56%
60-69 years	9	20.93%
70+ years	11	25.58%
Female	30	69.77%
Race/Ethnicity		
Asian	2	4.65%
Black of African American	1	2.33%
White or Caucasian	36	83.72%
Other	4	9.30%
Education		
Less than high school	2	4.65%
High school diploma (including GED)	5	11.63%
Some College to College Grad	20	46.51%
Post College	16	37.21%
Type 2 Diabetes	30	70.00%
Income		
Less than $5,000 - $39,000	9	20.93%
$40,000 - $59,000	10	23.26%
$60,000 - $99,000	9	20.93%
$100,000+	8	18.60%
Don't know	7	16.28%

Table 3. Test-retest Reliability

BAT Variable	% Agree	r	p
servfruitveg	89	0.71	<0.0001
eat3meals	68	0.37	0.0224
restaurant	74	0.78	<0.0001
physactivity	79	0.59	0.0001
modtostren	58	0.58	0.0001
smbg	92	0.93	<0.0001
missmeds	76	0.27	0.0983
depressed	87	0.64	<0.0001
nopleasure	92	0.71	<0.0001
alcohol	97	0.95	<0.0001
concernalc	97	0.98	<0.0001
smoke	95	0.96	<0.0001
selfratehealth	79	0.83	<0.0001
eyeexam	100	-	-
checkfeet	68	0.42	0.008
footexam	97	0.81	<0.0001
havefamfriends	97	-	-
famfriendsnear	87	0.55	0.0034
support	61	0.58	0.0001
vision	68	0.29	0.1946
hearing	95	0.81	<0.0001
walking	97	0.97	<0.0001
remembering	87	0.79	<0.0001
probpaymeds	0.95	0.84	<0.0001
probpayfood	0.92	0.37	0.0233
probpaytransport	0.89	0.62	0.0001
probpaysmbg	0.95	0.75	<0.0001

CONCLUSION:

For most BAT questions, test-retest reliability is acceptable and suitable for clinical use (r ? 0.50). However, it is lower for the questions "eat3meals" (r = 0.37), "missmeds" (r = 0.27), "checkfeet" (r = 0.42), "vision" (r = 0.29), and "probpayfood" (r = 0.37).

Further study is required to determine: a) whether the low reliability is specific to this sample; and b) possible reasons for the low reliability scores, such as question wording. Data collected from other sites might shed light on the first issue, and ongoing studies of the BAT's validity may address the issue of question wording.